HomeCare Services

DirectAccess Online Tool

NURSE REFERENCE GUIDE

Baxter

WELCOME

...from Baxter's HomeCare Services team.
Whether we are taking orders, delivering products or answering your questions, our job is to assist you and your patients with home dialysis needs. We will work with you to set up new patients, maintain patient prescriptions and order/deliver your patient's dialysis supplies.

Baxter provides consistent, high quality products and services to our home patients and health care professionals. The cooperation between you and Baxter are key components of success.

There are several key interactions you will experience with Baxter's HomeCare Services team, including the following:

- New Home Patients
- Basic Services
- Other Patient Orders & Changes
- Other Patient Services
- Center Professional Needs

Because many of these interactions apply to both home patients and health care professionals, you will find information applicable to both audiences in our *Going Home with Confidence* booklet. For information specific to health care professionals, we have the **DirectAccess** online tool which was designed to help you manage your patients more efficiently than ever before. The sections in this guide provide step by step instructions on how to use the **DirectAccess** online tool. This is the preferred vehicle for health care professionals to manage home patient transactions with Baxter.

We strive to deliver superior service that promotes value and makes a meaningful difference in our customer's lives.

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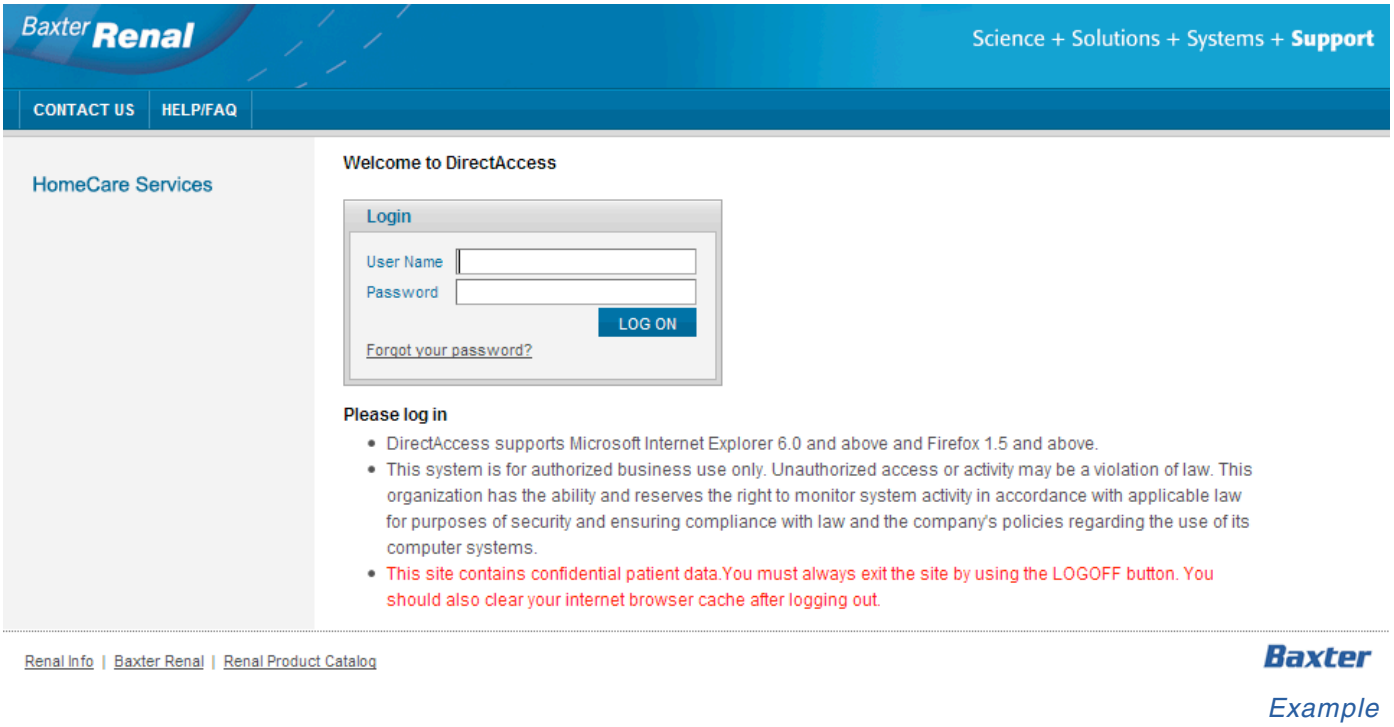
HomeCare Services

Logon and Navigation

DirectAccess Online Tool Logon and Navigation

LOGON

Use your browser (Internet Explorer 6.0 and above and Firefox 1.5 and above) to go to the login page of the **DirectAccess** online tool using the link you receive from Baxter's HomeCare Services.


Baxter Renal
Science + Solutions + Systems + Support
CONTACT US
HELP/FAQ
HomeCare Services
Welcome to DirectAccess
Login
User Name
Password
LOG ON
Forgot your password?
Please log in
DirectAccess supports Microsoft Internet Explorer 6.0 and above and Firefox 1.5 and above.
This system is for authorized business use only. Unauthorized access or activity may be a violation of law. This organization has the ability and reserves the right to monitor system activity in accordance with applicable law for purposes of security and ensuring compliance with law and the company's policies regarding the use of its computer systems.
This site contains confidential patient data.You must always exit the site by using the LOGOFF button. You should also clear your internet browser cache after logging out.
Renal Info | Baxter Renal | Renal Product Catalog
Baxter

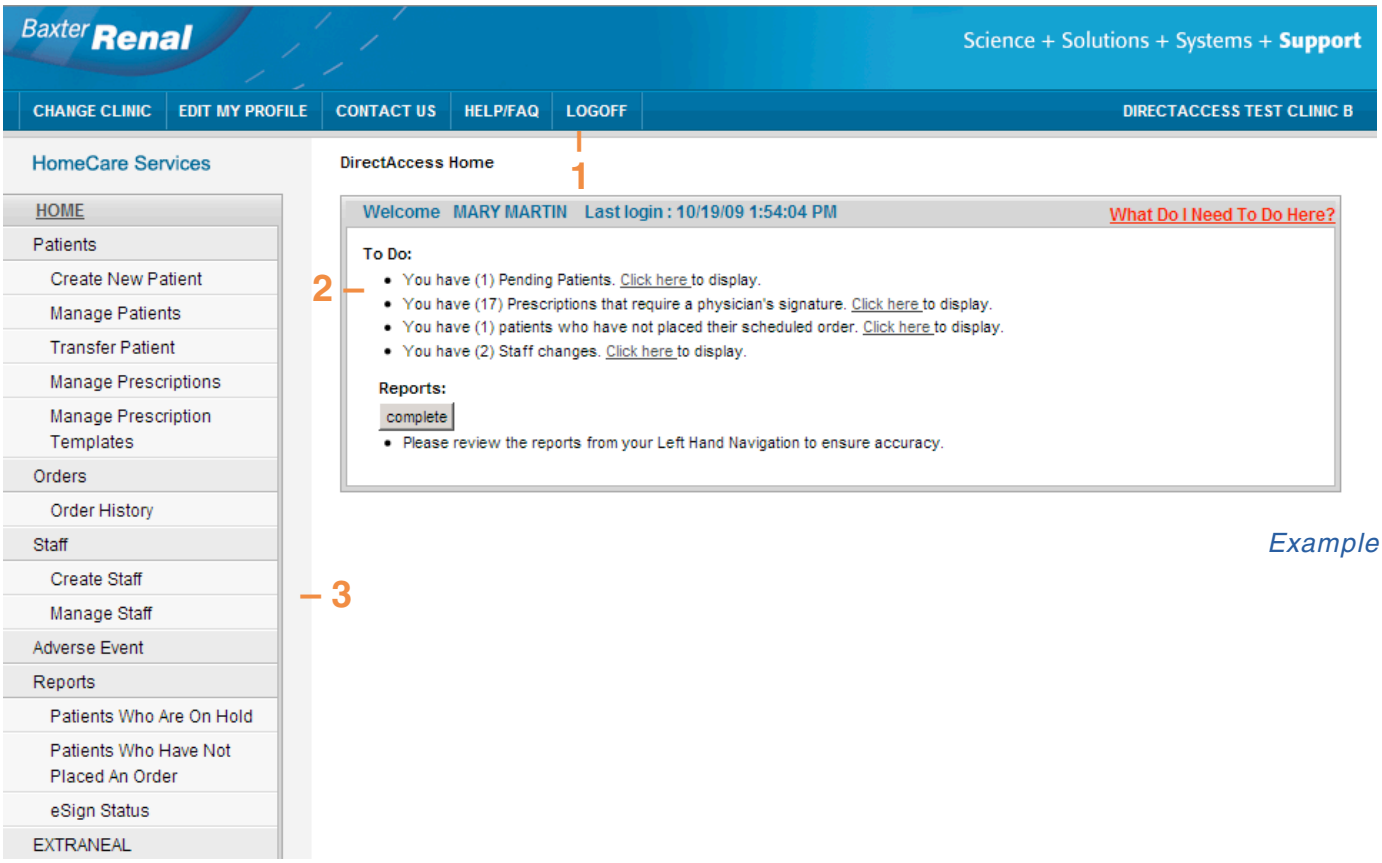
Example

Enter your user name and password and click LOGON.

NOTE: Remember that your user name and password are case sensitive.

NAVIGATION

The system displays the Home Page of the **DirectAccess** online tool.



Example

SCREEN LAYOUT

1. Basic Menu Options - At the top are basic menu options. This includes a Change Clinic option, which is only available if you have access to multiple clinics. The name of the clinic you are currently viewing is listed on the far right. If you have this option, click on it and a pop-up window will allow you to switch between the Clinics to which you have access. Additional menu options include access to your User Profile, Contact Information, Help/FAQ and the Log Off option.

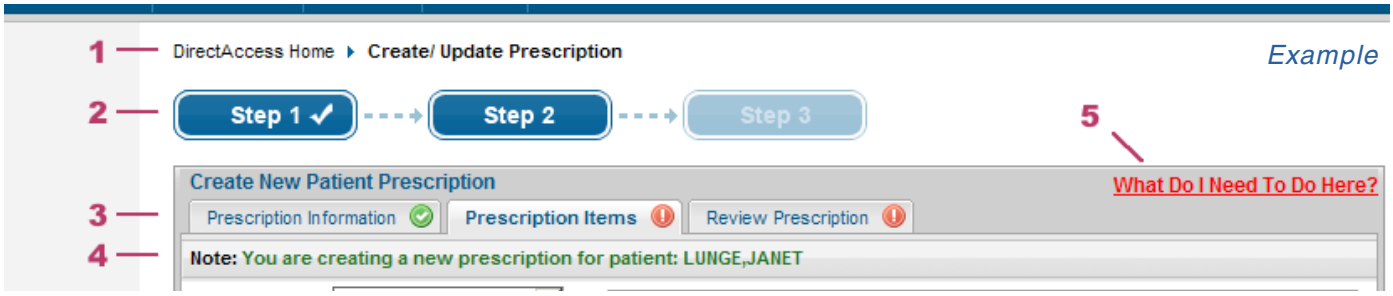
2. To Do List - The To Do list provides a constantly updated queue of matters requiring your attention. For example, it includes a list of patients whose information or prescriptions are incomplete, a list prescriptions that are new, updated or need to be renewed, and a list of patients who have not placed their scheduled orders.

Each staff member's To Do list is unique and changes constantly based on their actions and the actions of other staff members. For example, if you have a prescription for one of your patients that requires renewal, it will show up on your To Do list. Once you renew the prescription and send it for a physician's signature, it will show up on the physician's To Do list.

3. Navigation Bar - The navigation bar on the left of each screen allows you access to all the functions in the system. This includes a link to return to the Home screen and links to manage patients, prescriptions, orders, staff, adverse affects, and reports. It also includes links to important information about **Extraneal** (icodextrin) PD solution.

HELPFUL SCREEN TIPS

The following screen tips will help you take advantage of the information and navigation aids built into the screens of the **DirectAccess** online tool.



Example

1. The Breadcrumb - shows you where in the system you are in relation to the Home screen.
2. The Steps show you how you're progressing through a set of tabs on a screen.
3. The Tabs show the types of information and the Icons on the tabs show whether the information is complete (green checkmark) or requires work (red exclamation).
4. The Note indicates specific information, like the name of the patient you are working on and the related activity.
5. The What Do I Need To Do Here? link is provided on most pages. Click on this link for a demonstration of how to complete the tasks on that page. The link will be located in the upper right corner of the screen.

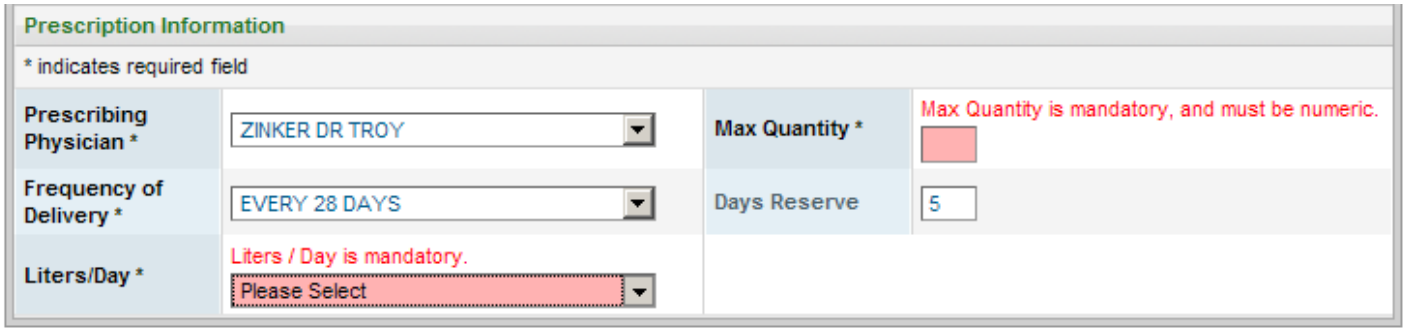
BUTTONS

Please use the buttons on the screen to navigate: rather than the buttons on the browser.

Example

ERRORS

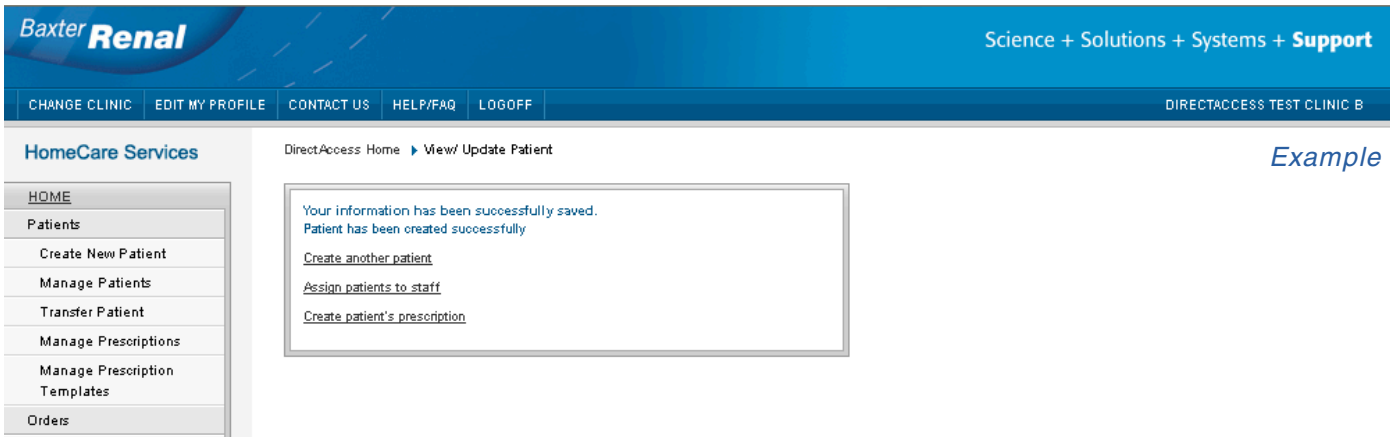
Error fields are identified in light red with an error message in red text.



Example

CONFIRMATION MESSAGES

When you complete a process, the system provides a confirmation window telling you the results of your action (e.g., that your information has been successfully saved). The system may also provide you with links to additional system functions.



Example

CANCELS

The system allows you to cancel a process prior to a Save by clicking the Cancel button.

For additional assistance at any time, please feel free to contact the **DirectAccess** technical support team at: 1-800-284-4060.

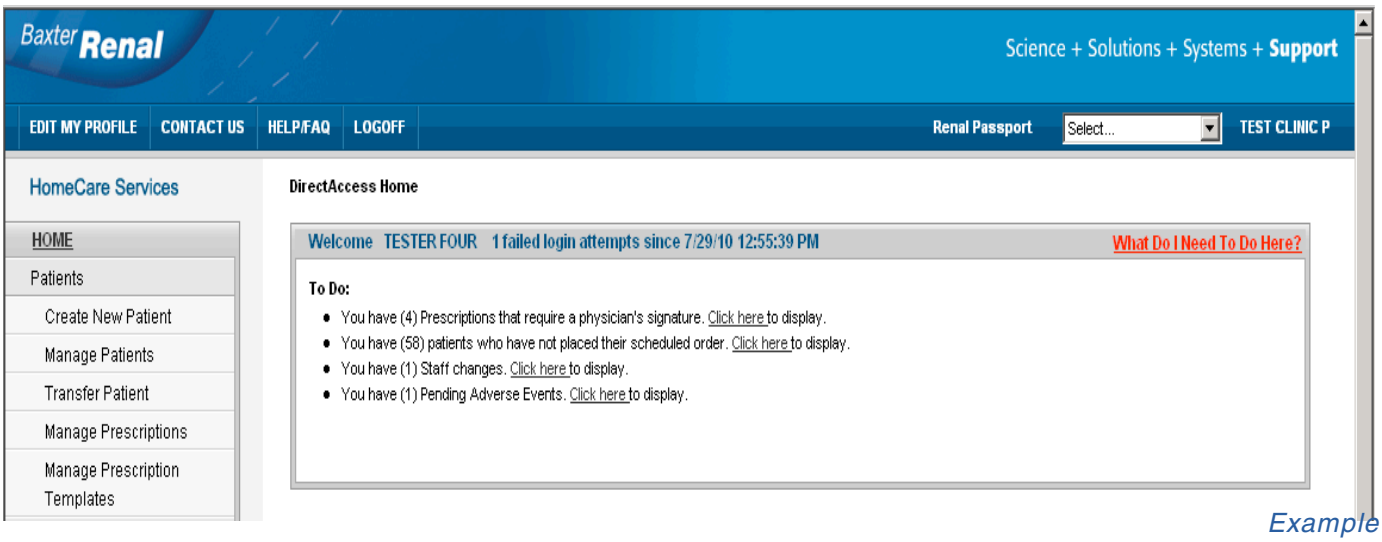
HomeCare Services

Create New Patient

Create New Patient

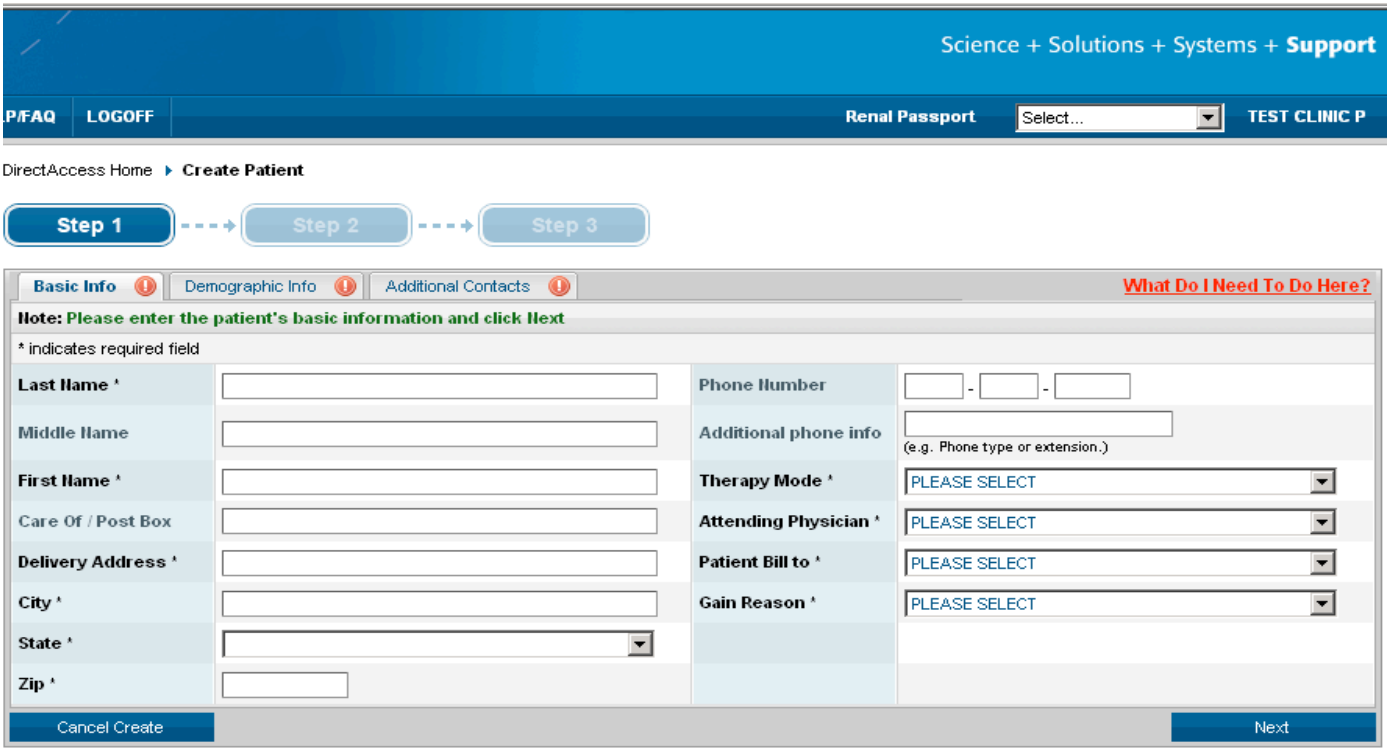
THE FOLLOWING STEPS WILL GUIDE YOU IN CREATING A NEW PATIENT.

Log on to the **DirectAccess** online tool. From the left navigation bar, select **Create New Patient**.


Baxter Renal
Science + Solutions + Systems + Support
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
Renal Passport
Select...
TEST CLINIC P
HomeCare Services
DirectAccess Home
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Welcome TESTER FOUR 1 failed login attempts since 7/29/10 12:55:39 PM
What Do I Need To Do Here?
To Do:
You have (4) Prescriptions that require a physician's signature. Click here to display.
You have (58) patients who have not placed their scheduled order. Click here to display.
You have (1) Staff changes. Click here to display.
You have (1) Pending Adverse Events. Click here to display.

Example

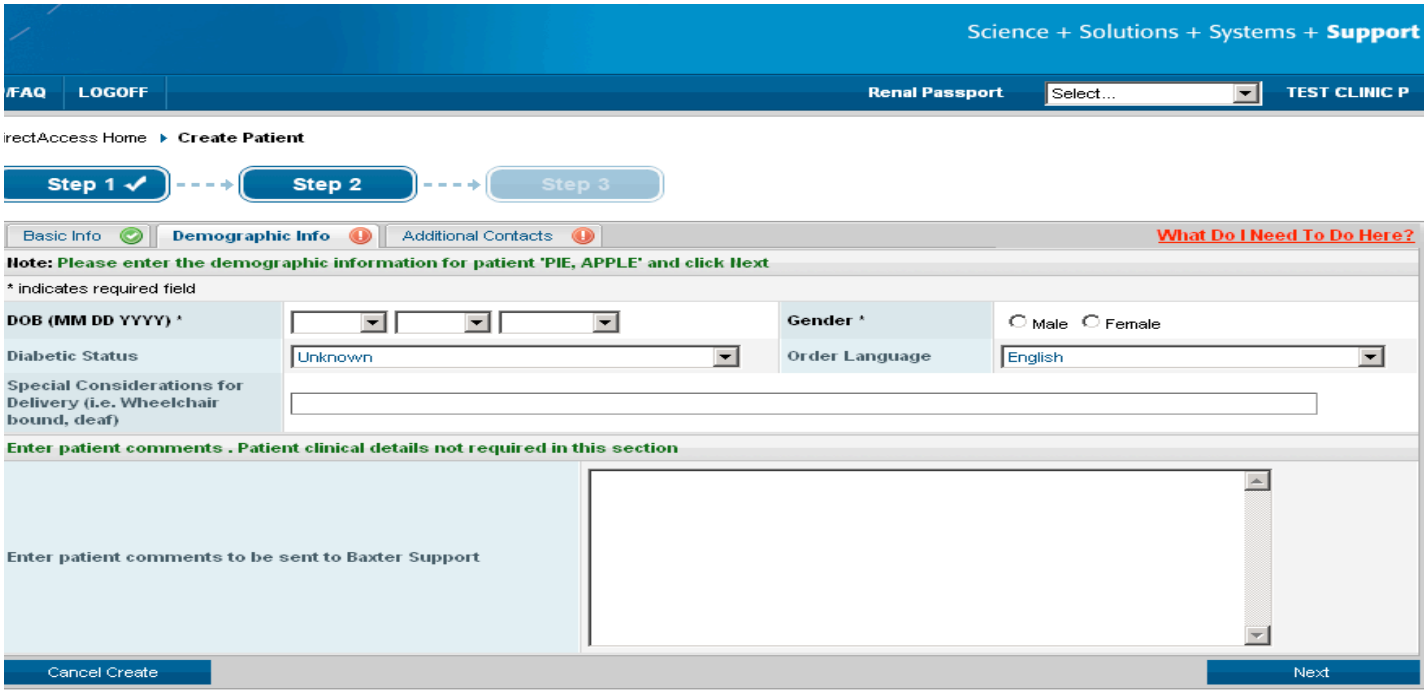
There are only three steps to setting up a new patient. The **Basic Info** tab displays first. Complete all of the fields and click **Next** to continue or **Cancel Create** to end the process.



Example

Click on **What Do I Need To Do Here** for additional help. This help option is located on each tab.

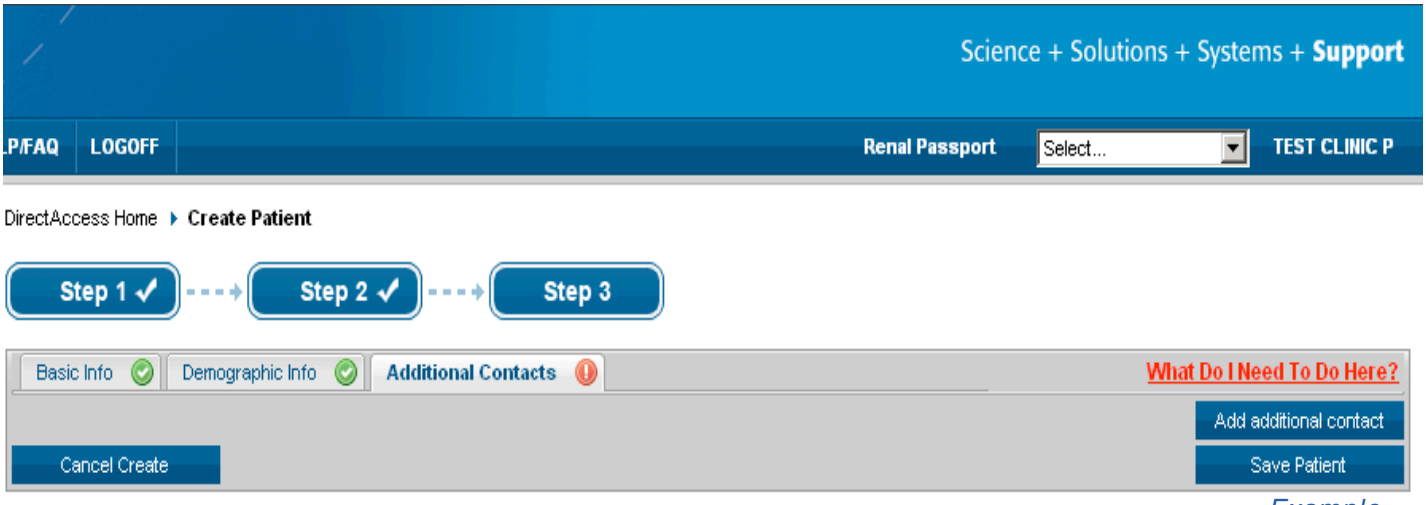
The **Demographic Info** tab displays. Complete all of the fields and click **Next** to continue or **Cancel Create** to end the process. The note tells you what patient you are entering.



Example

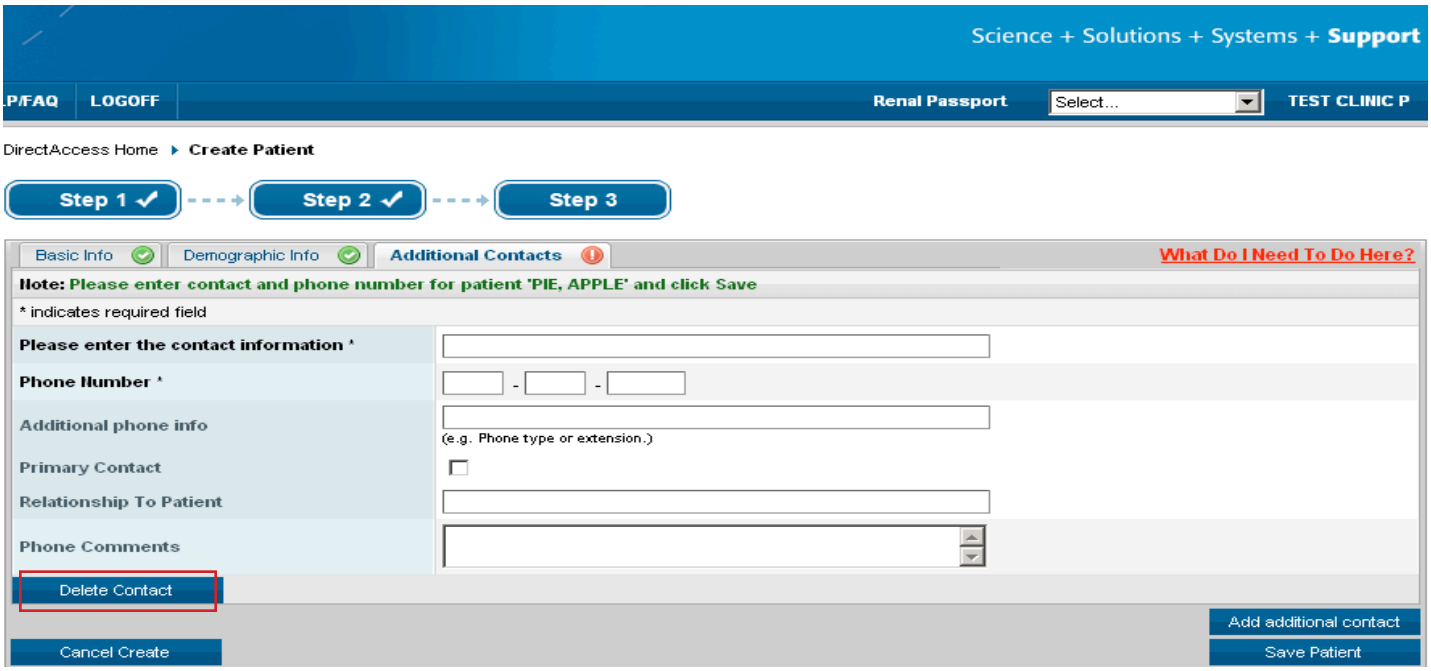
Notes can be entered in the free form text box. These notes will be sent to Baxter when clicking **Next**. This field can be utilized at any time for any patient to send Baxter information.

The **Additional Contacts** tab displays. You can select **Save Patient** to save with no additional contacts or **Cancel Create** to end the process. To add additional contacts, click **Add additional contact**.



Example

Complete all fields. To add multiple contacts, click **Add additional contact.** To delete a contact, click **Delete Contact**. Click **Save Patient** when you are finished adding additional contacts.



Example

The confirmation window displays. You can choose to **Create another patient**, **Assign patients to staff**, or **Create patient's prescription**. The patient will remain in your **To Do** list under **Pending Patients** until the prescription has been completed.

Example

You can access the Renal Product Catalog by clicking the link located at the bottom of the **DirectAccess** online tool HOME page.

For additional assistance at any time, please feel free to contact the **DirectAccess** technical support team at: 1-800-284-4060.

New Home Patients

NEW PATIENT SETUP

Please provide the following information when contacting Baxter to establish a new patient.

- Patient first and last name
- Patient address - *P.O. boxes are acceptable for mailings only. P.O. Boxes are not acceptable for supply deliveries. Please supply physical street address. If none available please include cross streets and detailed directions
- Patient phone number and back up phone number
- Gender
- Special Handling requests (i.e. wheelchair, blind, child or Spanish speaking)
- Gain Reason
  - 07Z=No prior mode
  - 01Z=From Chronic ICH
  - 02Z=From Acute ICH
  - 08Z=Transplant Failed
  - 13Z=Other
- Modality
  - CAPD
  - APD
  - Hemo
- Diabetic Status
  - N=No
  - U=Unknown
  - Type 1=Insulin dep
  - Type 2 =Non Insulin dep
  - Type 2=Insulin dep
  - D=Undisclosed
- Sold To Option
  - Method 1
  - Method 2
  - Baxter Supplied (BSS)
- Purchase Order # (if applicable)
- Attending Physician Name

PRESCRIPTION REQUIREMENTS

Baxter will not accept any order for patients without a prescription signed and dated by a physician.

THE INFORMATION REQUIRED FOR PRESCRIPTIONS INCLUDES:

1. Product codes and quantities
   - Utilize your product catalog to determine codes
2. 5B max and 5B Line maxes
   - Utilize the 5B solution grid to help set 5B maxes (Page 62)
3. Allowable refill period not to exceed one year
4. Prescriptions should be managed and e-signed through the **DirectAccess** online tool. Refer to Section 5 for more details.

? DID YOU KNOW

Baxter's product catalog can be accessed at
http://www.ecomm.baxter.com/ecatalog/browseCatalog.do

NEW PATIENT LEAD TIME GUIDELINES

Baxter requires a five business day lead time. This lead time:

- Will increase the likelihood that the delivery will be made by a Baxter Service Specialist
- Ensures patient receives introductory packet from Baxter before delivery
- Facilitates a minimum number of order shipments
- Ensures hardware (machines) [shipped separately from solutions] are received on or near the date of solutions delivery

Orders must be placed no later than 12 noon local time in the time zone of your local distribution center to be counted for a particular business day. Orders placed after 12 noon local time will be counted on the following business day for purposes of calculating lead time.

BENEFITS OF BAXTER TRUCK DELIVERY:

The following exemplify the delivery services provided by Baxter:

- New patient introduction (driver introduces self, explains ordering/inventory count process, reviews intro packet)
- Supplies are brought to correct area of home
- Rotation of patient's stock by Baxter Service Specialist upon request
- Call to patient prior to delivery indicating 3-hour delivery time window

If short lead delivery (<5 business days) is required, there may be multiple delivery shipments and the probability of having the delivery made by a Baxter Service Specialist decreases. Please remember that while we strive to have commercial carriers meet our delivery requirements, we cannot guarantee their delivery schedule.

? DID YOU KNOW

In 2008, almost 90% of our customers ranked willingness to have this driver or other carrier make future Baxter deliveries in the top two box satisfaction levels on a 9-point scale through our automated telephone surveys.

INITIAL ORDER PLACEMENT

Several orders may be placed at the time of initial set up:

- Initial Order to the patient containing solution, ancillaries (i.e. gauze) and supporting product (i.e. caps or lines)
- Starter Kit to the patient or unit (i.e. IV pole, scale or BP cuff)
- Training supplies to the patient or unit following your established contract
- Hardware to the unit (i.e. **HomeChoice** APD system)

Templates are available in the **DirectAccess** online tool to customize prescriptions based on your clinic's needs.

DID YOU KNOW

- If you are placing an order mid cycle you may need to increase or decrease the order quantities to get the patient on a scheduled delivery route.
- Together with your HCSR we can ensure your new patient's first experience with Baxter is with a Baxter driver whenever possible. Your Baxter HCSR can provide with information regarding when the next Baxter truck is in your new patient's area.

THE NEW PATIENT INTRODUCTORY PACKET

When your new home patient is set up with Baxter, an introductory packet will be mailed to the patient. This packet includes the following materials intended to help the patient understand how to place orders, manage inventory and interact with Baxter:

- Going Home with Confidence
- Home Patient Inventory Form
- Home Patient Order and Delivery Schedule
- Global Destinations Postcard
- Emergency Preparedness Brochure

A sample of the Home Patient Inventory Form is available in this booklet (See Appendix C). You can request a copy of the *Going Home with Confidence* booklet from your Baxter Account Executive or Clinical Educator.

OTHER TOOLS AVAILABLE TO HELP YOU

Utilizing the following order placement tools will assist in making ordering and processing times more efficient and will improve order accuracy.

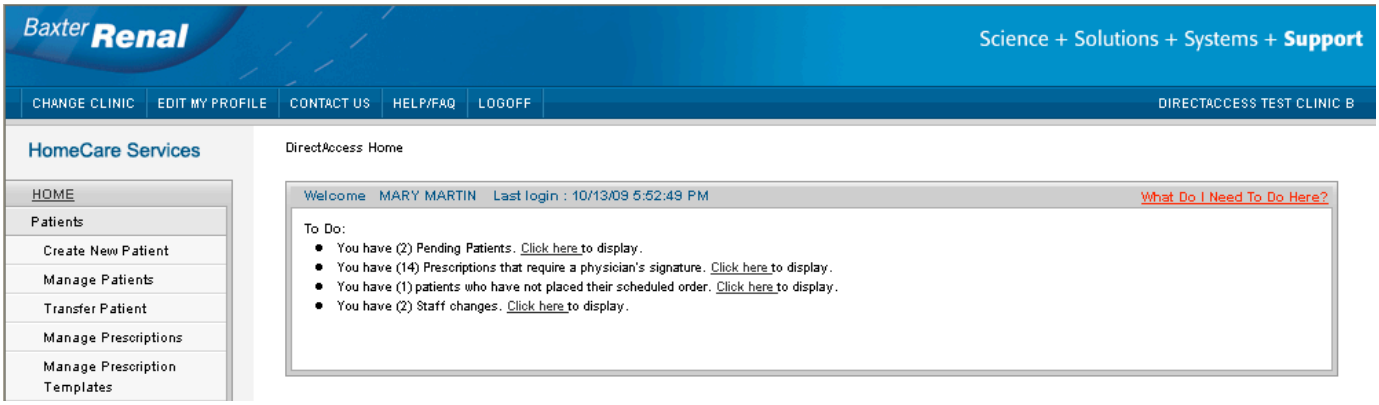
- **Product Catalog**
  Please use Baxter product codes whenever possible when placing orders. The Baxter product catalog can be accessed at http://www.ecomm.baxter.com/ecatalog/browseCatalog.do
- **5B Max Grid** (Page 62)
  The Maximum Solution Case or 5B Max Quantity found in the upper right hand corner of the Baxter Ordering Grid, refers to the overall maximum number of solution cases a patient is allowed to receive in his or her delivery cycle. An optimal 5B Max assists in managing the home patient's inventory while allowing the patient to vary ratios without exceeding the total number of allowed cases within the cycle. The 5B Max grid was designed to help the facility calculate how much solution a patient may need for a 28-day cycle
- **Baxter Ordering Grid** (Appendix D)

HomeCare Services

Pending Patients

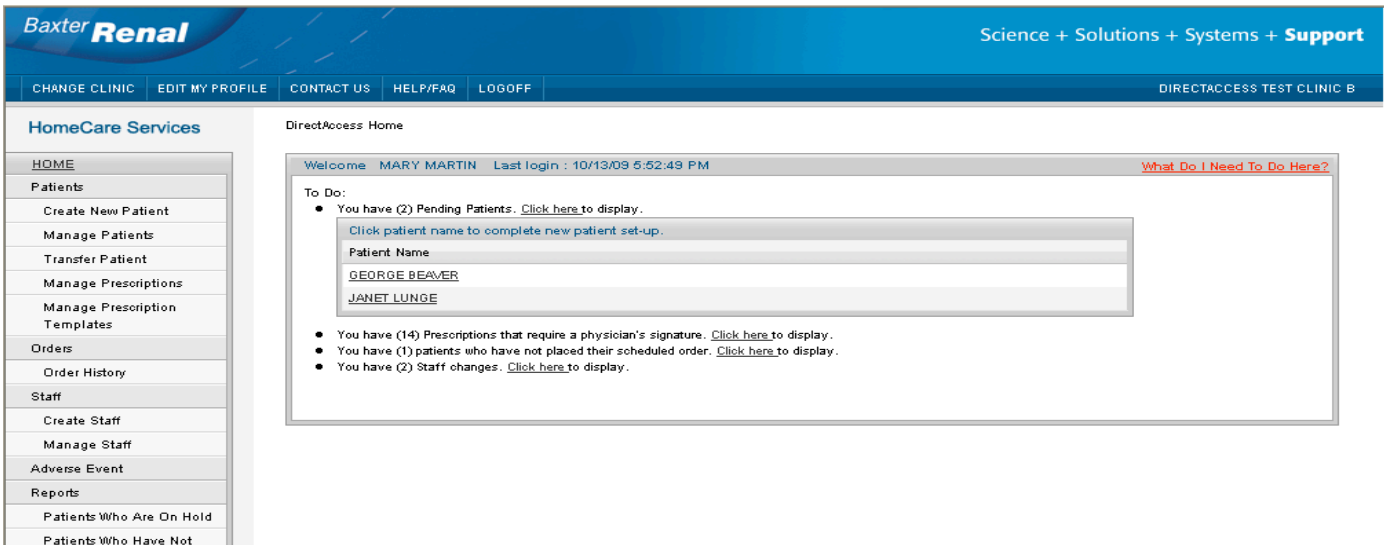
Pending Patients

After logging on, the system displays the **DirectAccess** online tool Home Page. Pending Patients are defined as incomplete patient setup and the To Do item indicates actions required to complete patient setup.


Baxter Renal
Science + Solutions + Systems + Support
CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
DirectAccess Home
Welcome MARY MARTIN Last login : 10/13/09 5:52:49 PM
What Do I Need To Do Here?
To Do:
You have (2) Pending Patients. Click here to display.
You have (14) Prescriptions that require a physician's signature. Click here to display.
You have (1) patients who have not placed their scheduled order. Click here to display.
You have (2) Staff changes. Click here to display.

Example

1. To see a list of these patients, click the **Click Here** link to display; the system displays the patients in a box below the link you just clicked.



Example

2. To complete the pending work on a patient, click the patient's name in the box. The system will start you at one of the following tabs of the **View/Update Patient Screen**, or at the **Create/Update Prescription Screen** (explained below), depending on what is required to complete the pending patient set up.

VIEW/UPDATE PATIENT SCREEN

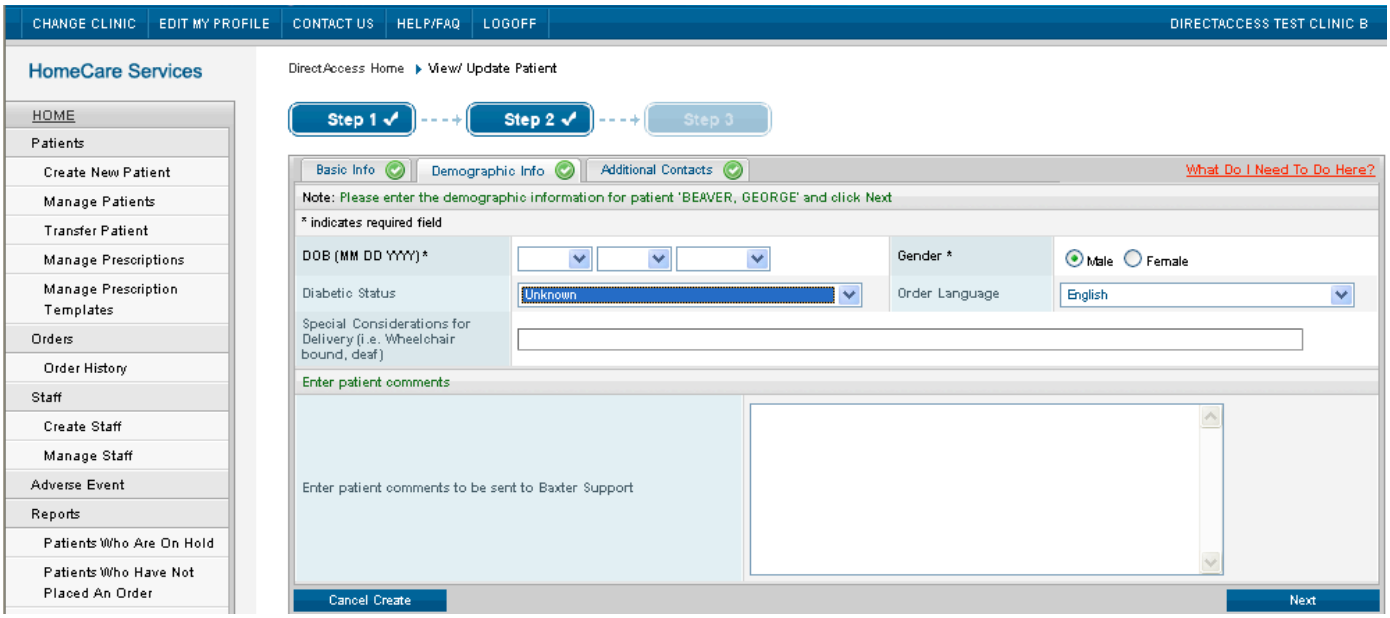
The View/Update Patient Screen has three tabs:

- Basic Info tab
- Demographics Info tab
- Additional Contacts tab

> You will not be directed to the **Basic Info** tab of the **View/Update Patient Screen** because that information will be complete. But you can view it if you wish by clicking on the tab.

VIEW/UPDATE PATIENT SCREEN - DEMOGRAPHICS INFO TAB

The system displays the Demographics Info tab if this information is needed. The Note indicates the patient you are working on.

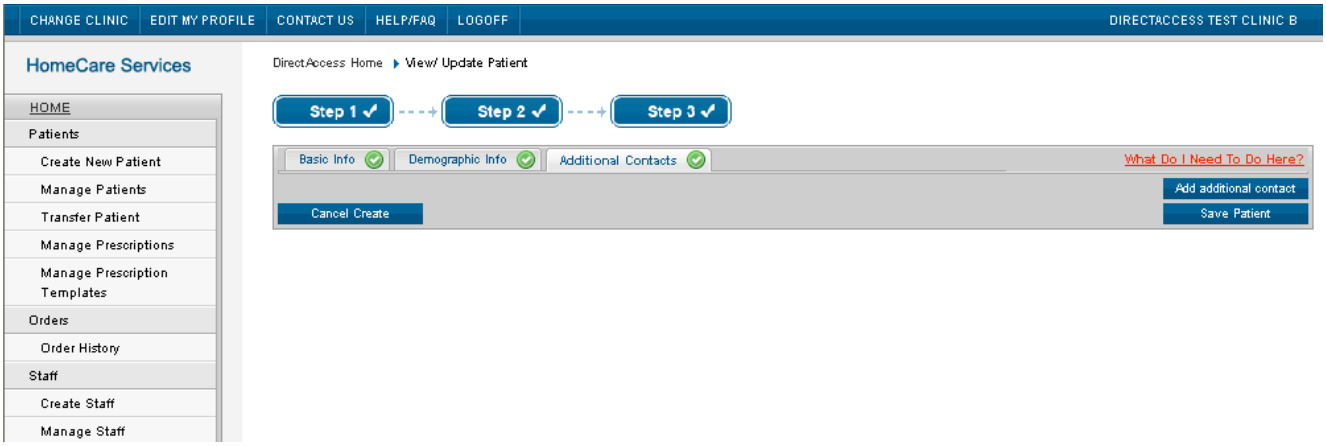


Example

3. Complete all required fields and add any additional comments or information as desired and click **Next.**

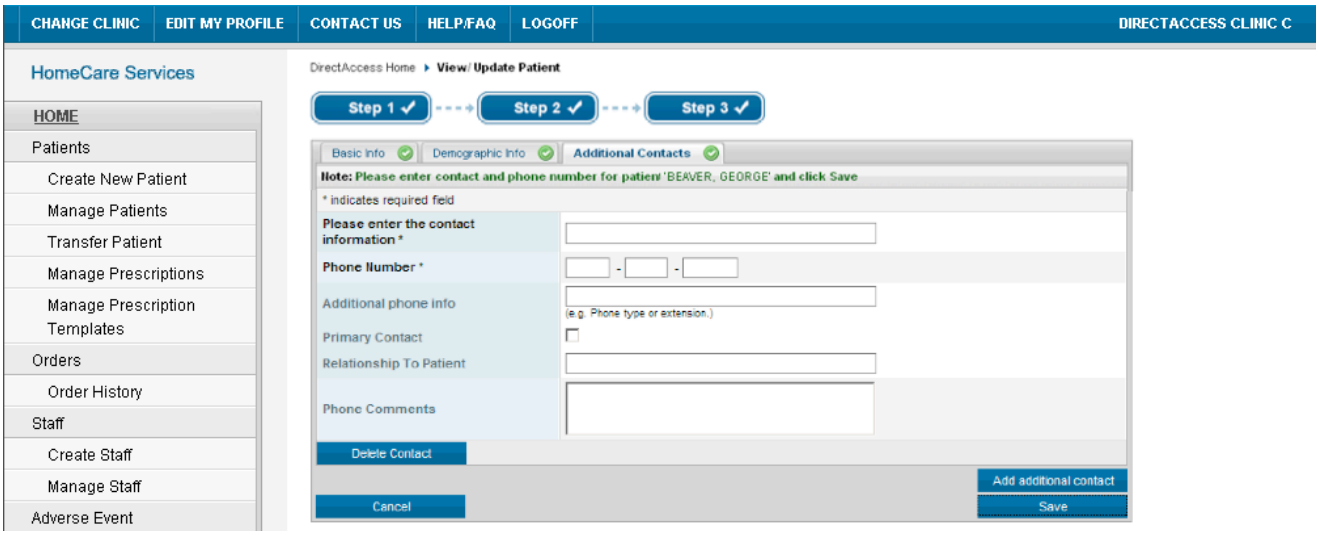
VIEW/UPDATE PATIENT SCREEN - ADDITIONAL CONTACTS TAB

The system displays the **Demographics Info** tab if this information is needed.



Example

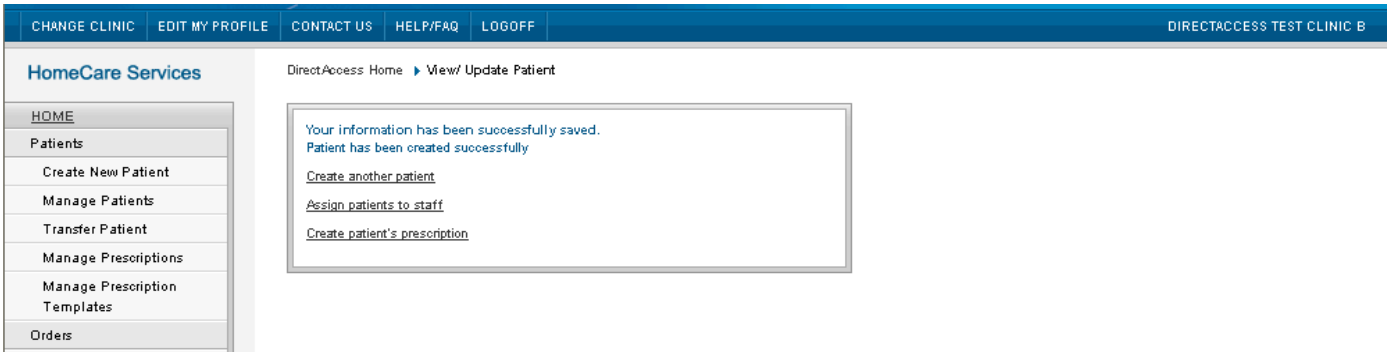
4. If you wish to add contacts, click the Add Additonal Contacts button; the system displays the **Additional Contact** screen. Enter the additional contact information.



Example

Information in the **Phone Comments** field is for clinic use only and is not accessible to Baxter.

5. When you are done adding additional contacts, click on **Save Patient**. The system displays a confirmation window with a message telling you that your information has been successfully saved and that the patient has been created successfully.



Example

6. Click the Create Patient's Prescription link to continue if prescription information is also required for that patient; this will take you to the Prescriptions section of the system. You can also get to it from the left hand navigation bar under Manage Prescriptions. Also, the patient's name will remain in the pending patient To Do list until the prescription is complete.

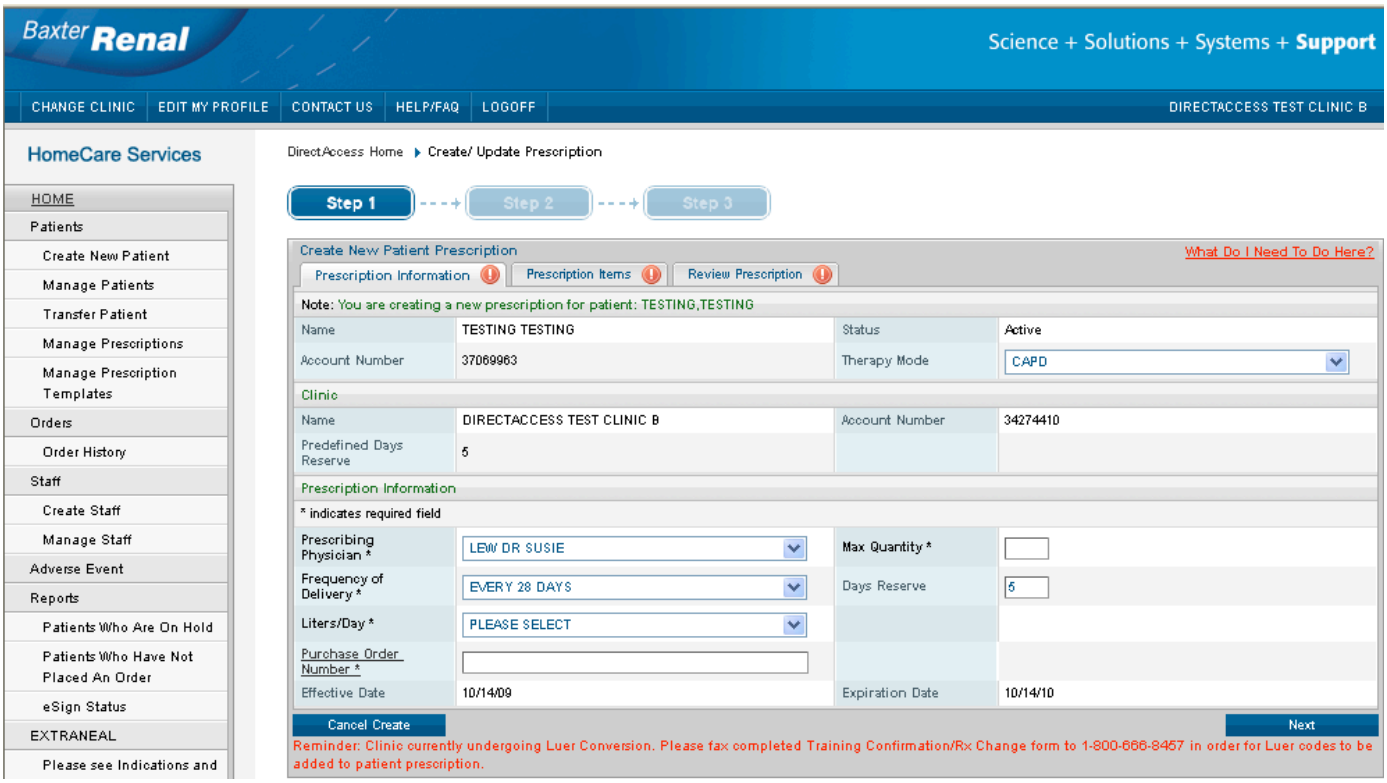
CREATE/UPDATE PRESCRIPTION SCREEN

The Create/Update Prescription screen has three tabs:

- Prescription Information
- Prescription Items
- Review Prescription

CREATE/UPDATE PRESCRIPTION SCREEN - PRESCRIPTION INFORMATION TAB

The system displays the **Prescription Information** tab if this information is needed.

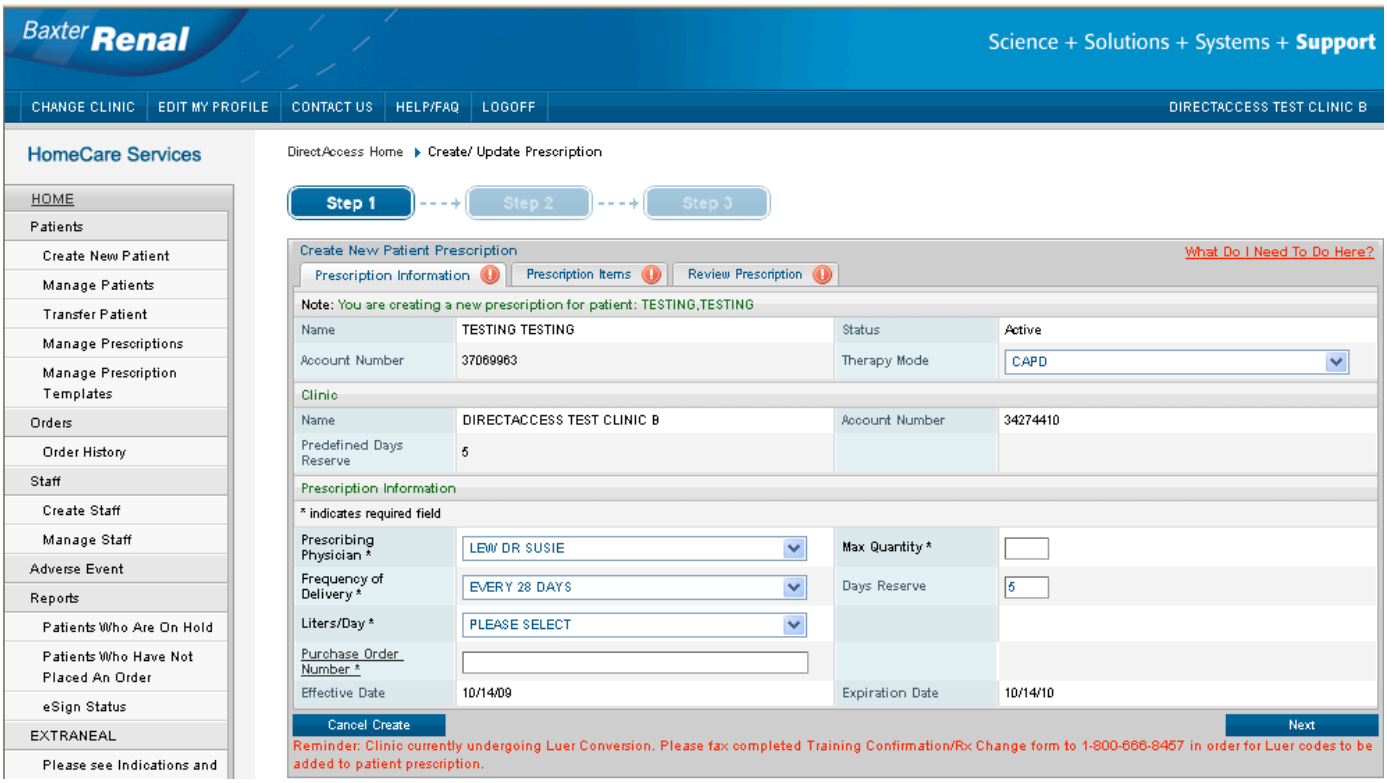


Example

7. Enter all required fields on the Prescription Information tab; a "*" next to the field name indicates that it is a required field. When you are done entering the information, click **Next.**

CREATE/UPDATE PRESCRIPTION SCREEN - PRESCRIPTION ITEMS TAB

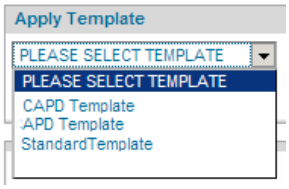
The system displays the **Prescription Items** tab if this information is needed.



Example

8. You can create the prescription either by using a template or creating it by adding the items from the **List of Items** on the left to the **Prescription Cart** (like a shopping cart) on the right.

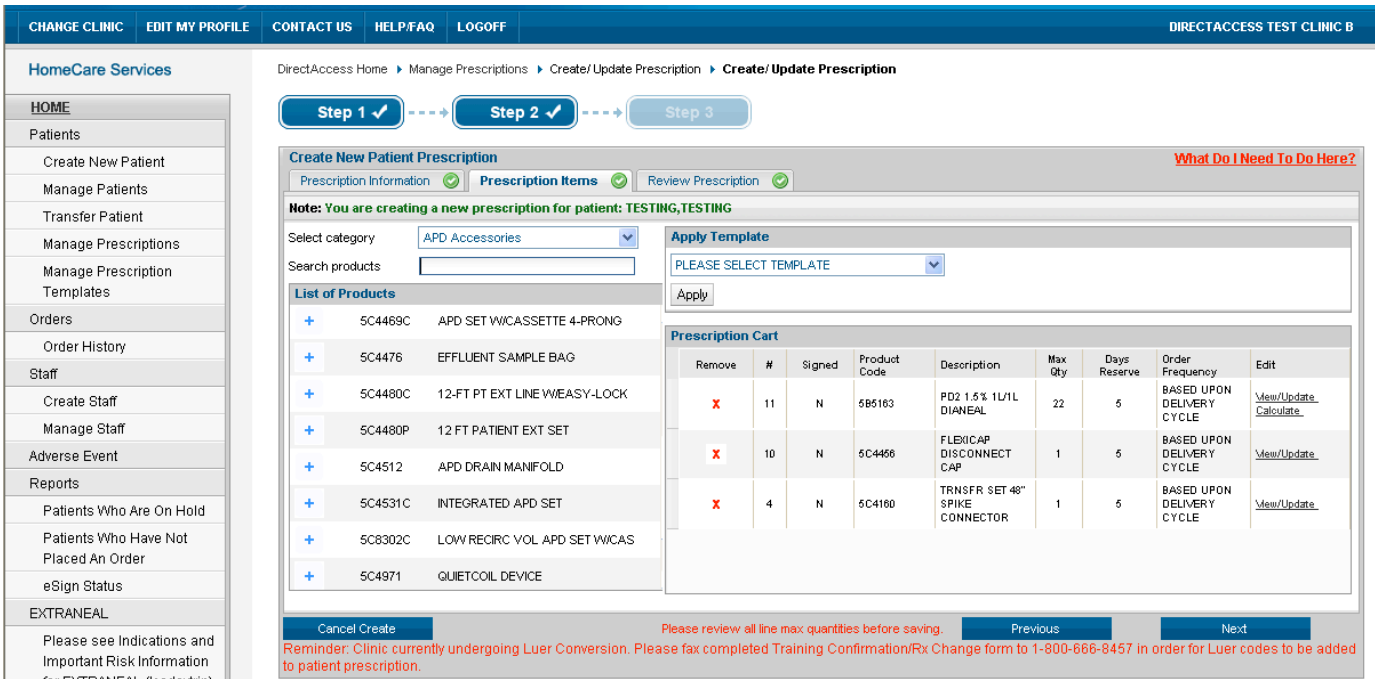
   Template - To use a template, select the template from the drop-down list in the **Apply. Template** box and click **Apply**; the system adds the items in the template to the **Prescription Cart**.



List of Products by Category - To populate the List of Products, select a category of products from the Category dropdown; this adds all the items in the category to the List of Products.

> You can also add products to the list by entering a search term in the **Search Products** box under the drop-down.

9. With the **List of Products** populated, you can move items from it to the **Prescription Cart**. You can also remove items from the **Cart**.



Example

To move an item from the **List of Products** to the **Prescription Cart**, click on the + symbol; the system will move the item to the **Prescription Cart**.

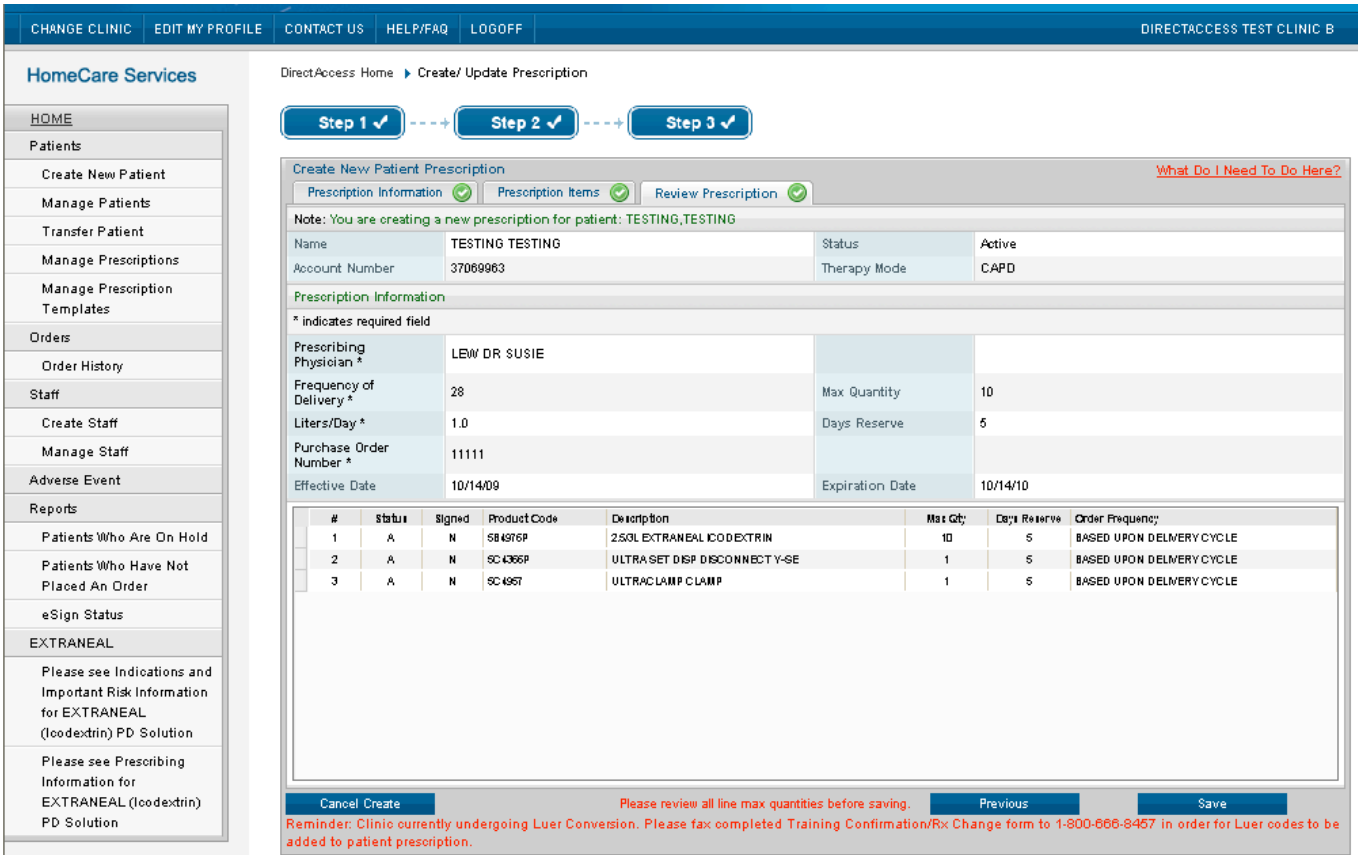
To remove an item from the **Prescription Cart**, click the X symbol in the **Remove** column; the system removes the item.

Click **View/Update** to change the line quantity on an item. Click **Calculate** to calculate how many boxes a patient will need for their delivery cycle based on how many bags per day they will be using.

10. When you are done, click **Save**.

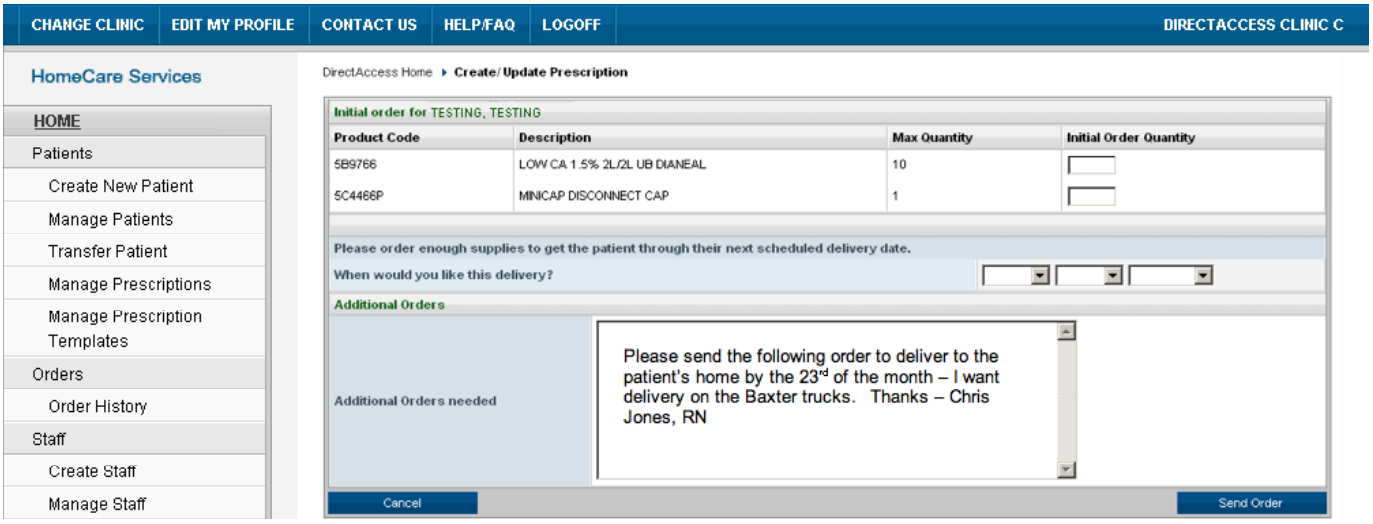
CREATE/UPDATE PRESCRIPTION SCREEN - REVIEW PRESCRIPTION TAB

The system displays the **Review Prescription** tab for your review



Example

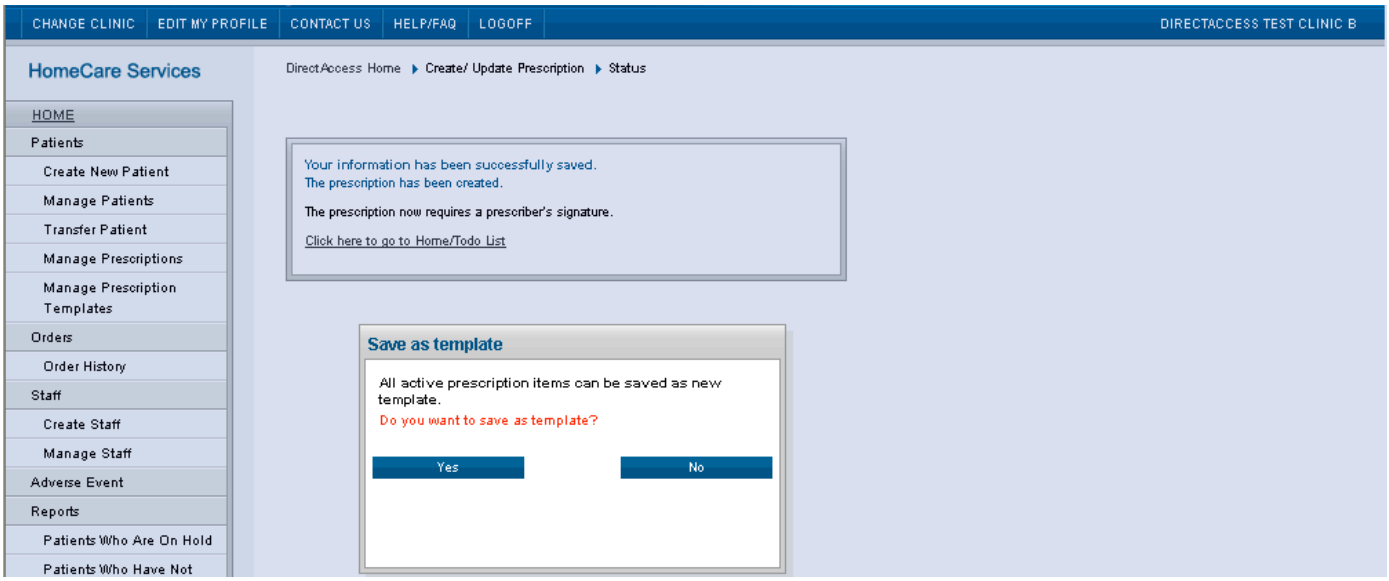
11. Review the prescription and return to the Prescription Items tab by clicking **Previous** if you need to make a correction. When you are done, click **Save**.



Example

CREATE/UPDATE PRESCRIPTION SCREEN - INITIAL ORDER SCREEN

The system displays the **Initial Order** screen.



Example

12. Enter instructions for HomeCare Services on what to send for the patient's first home delivery and click **Send Order**. The system displays the Confirmation screen.

    The system tells you that your information has been successfully saved and the prescription has been created. The prescription now requires a prescriber's signature; either esignature or handwritten signature on printed prescription is acceptable.

    The system also asks if you wish to save the prescription as a template. If you select **Yes**, you can use it as a starting point for other prescriptions.

    E-signing within **DirectAccess** online tool allows physicians to attach e-signatures to prescriptions. This is the preferred method for signing prescriptions. Refer to Section 5 for more details.

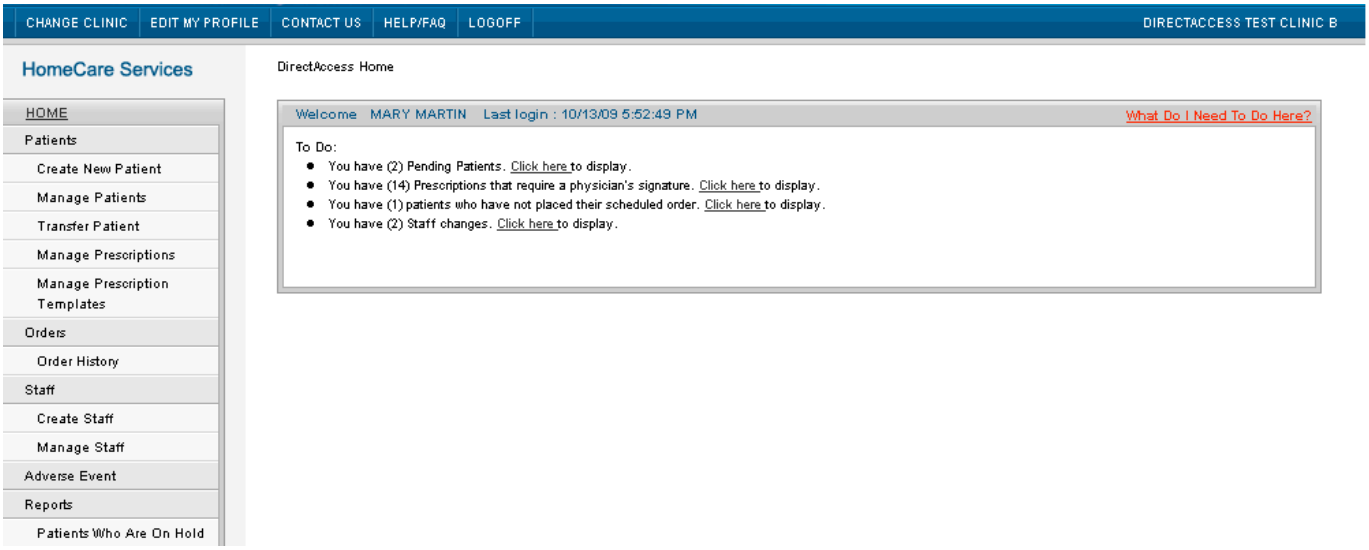
    To return to the To Do list, click **Home** from the left navigation bar.

HomeCare Services

Prescriptions

Prescriptions

After logging on, the system displays the **DirectAccess** online tool Home Page. An item on the **To Do** list identifies the prescriptions that require attention.



Example

Prescription To Dos may consist of:

- Recent prescription changes requiring a prescriber's review and signature
- New patient prescriptions requiring a prescriber's review and signature
- Annual Renewals requiring updates and a prescriber's review and signature

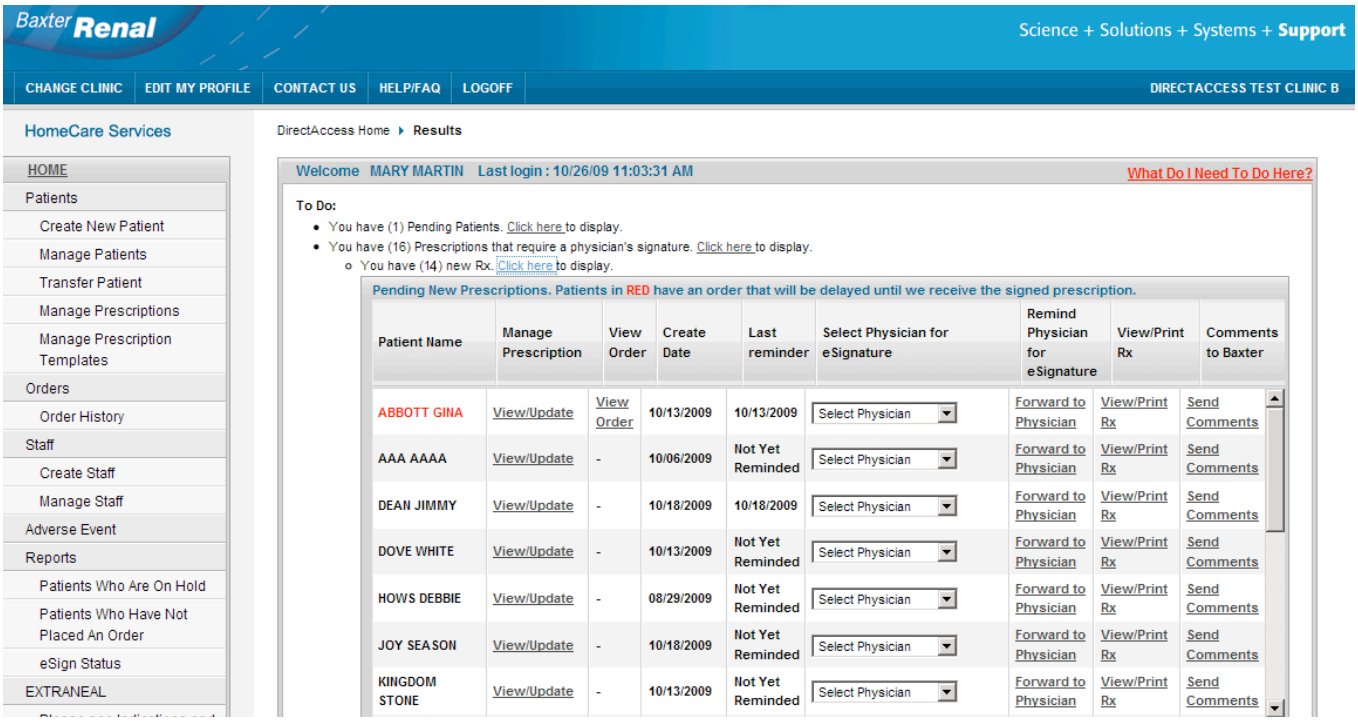
To see the Prescriptions list, click the **Click Here link** to display; the system displays lines identifying the number of new and changed prescriptions and those requiring a renewal, each with a **Click Here link**.

Baxter Renal
Science + Solutions + Systems + Suppo
CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
DirectAccess Home
Welcome MARY MARTIN Last login : 10/14/09 11:45:42 AM
What Do I Need To Do Here?
To Do:
You have (2) Pending Patients. Click here to display.
You have (16) Prescriptions that require a physician's signature. Click here to display.
You have (14) new Rx. Click here to display.
You have (1) changed Rx. Click here to display.
You have (1) renewal Rx. Click here to display.

Example

NEW AND CHANGED PRESCRIPTIONS

1. Click the **Click Here** link to display the new or the changed prescriptions; the system displays the prescriptions in a box below the link you just clicked.


Baxter Renal
Science + Solutions + Systems + Support
CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Orders
Order History
Staff
Create Staff
Manage Staff
Adverse Event
Reports
Patients Who Are On Hold
Patients Who Have Not Placed An Order
eSign Status
EXTRANEAL
DirectAccess Home ▸ Results
Welcome MARY MARTIN Last login : 10/26/09 11:03:31 AM
What Do I Need To Do Here?
To Do:
You have (1) Pending Patients. Click here to display.
You have (16) Prescriptions that require a physician's signature. Click here to display.
You have (14) new Rx. Click here to display.
Pending New Prescriptions. Patients in RED have an order that will be delayed until we receive the signed prescription.
Patient Name | Manage Prescription | View Order | Create Date | Last reminder | Select Physician for eSignature | Remind Physician for eSignature | View/Print Rx | Comments to Baxter
ABBOTT GINA | View/Update | View Order | 10/13/2009 | 10/13/2009 | Select Physician | Forward to Physician | View/Print Rx | Send Comments
AAA AAAA | View/Update | - | 10/06/2009 | Not Yet Reminded | Select Physician | Forward to Physician | View/Print Rx | Send Comments
DEAN JIMMY | View/Update | - | 10/18/2009 | 10/18/2009 | Select Physician | Forward to Physician | View/Print Rx | Send Comments
DOVE WHITE | View/Update | - | 10/13/2009 | Not Yet Reminded | Select Physician | Forward to Physician | View/Print Rx | Send Comments
HOWS DEBBIE | View/Update | - | 08/29/2009 | Not Yet Reminded | Select Physician | Forward to Physician | View/Print Rx | Send Comments
JOY SEASON | View/Update | - | 10/18/2009 | Not Yet Reminded | Select Physician | Forward to Physician | View/Print Rx | Send Comments
KINGDOM STONE | View/Update | - | 10/13/2009 | Not Yet Reminded | Select Physician | Forward to Physician | View/Print Rx | Send Comments

Example

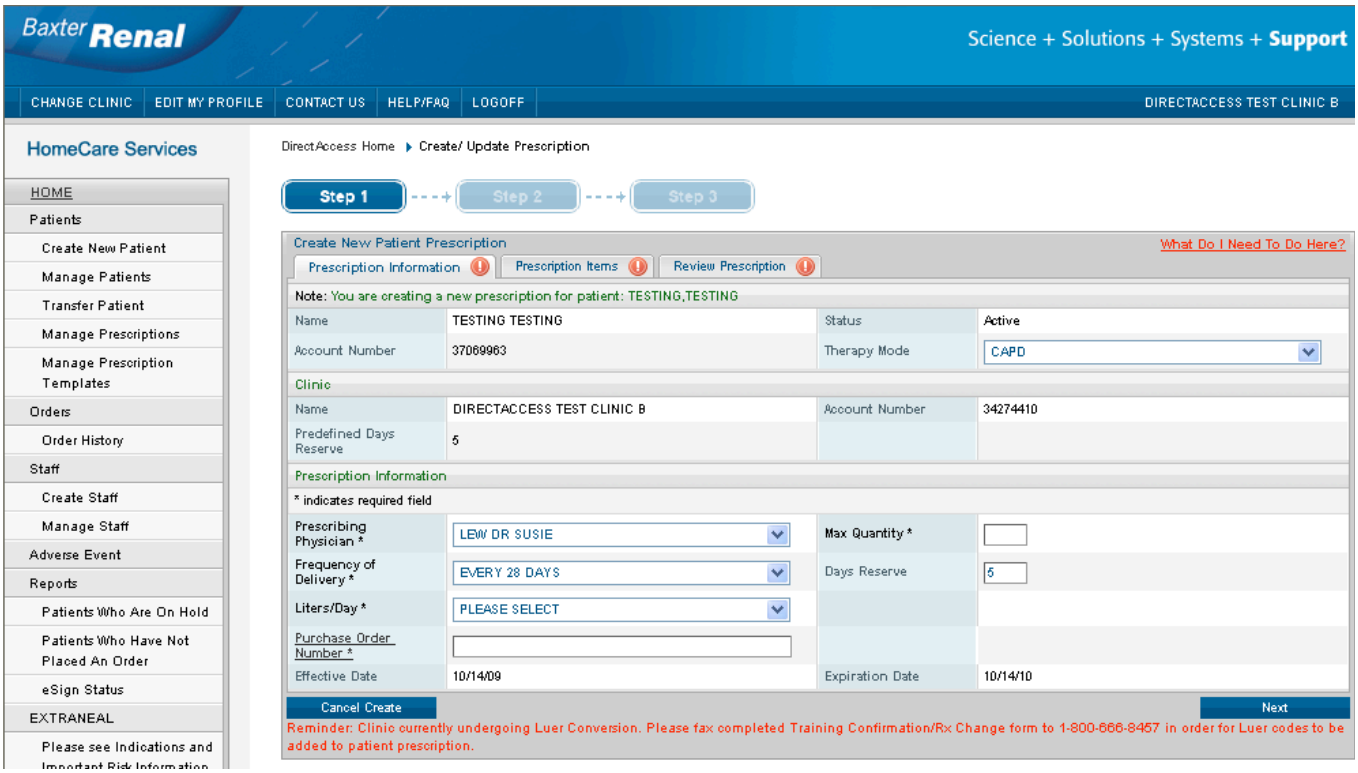
Names appearing in **Red** have orders that will be delayed until a signed prescription is received.

From this screen you can:

- View or Update the prescription
- View the order
- Select a physician to provide an eSignature for the prescription and forward the prescription to that physician
- View or Print the prescription
- Send Comments to Baxter

VIEW/UPDATE PRESCRIPTION

1. From the new or changed prescriptions box in the **To Do** list, click on the patient's **View/Update** link in the **Manage Prescriptions** column; the system displays the **Create/Update Prescription** screen.

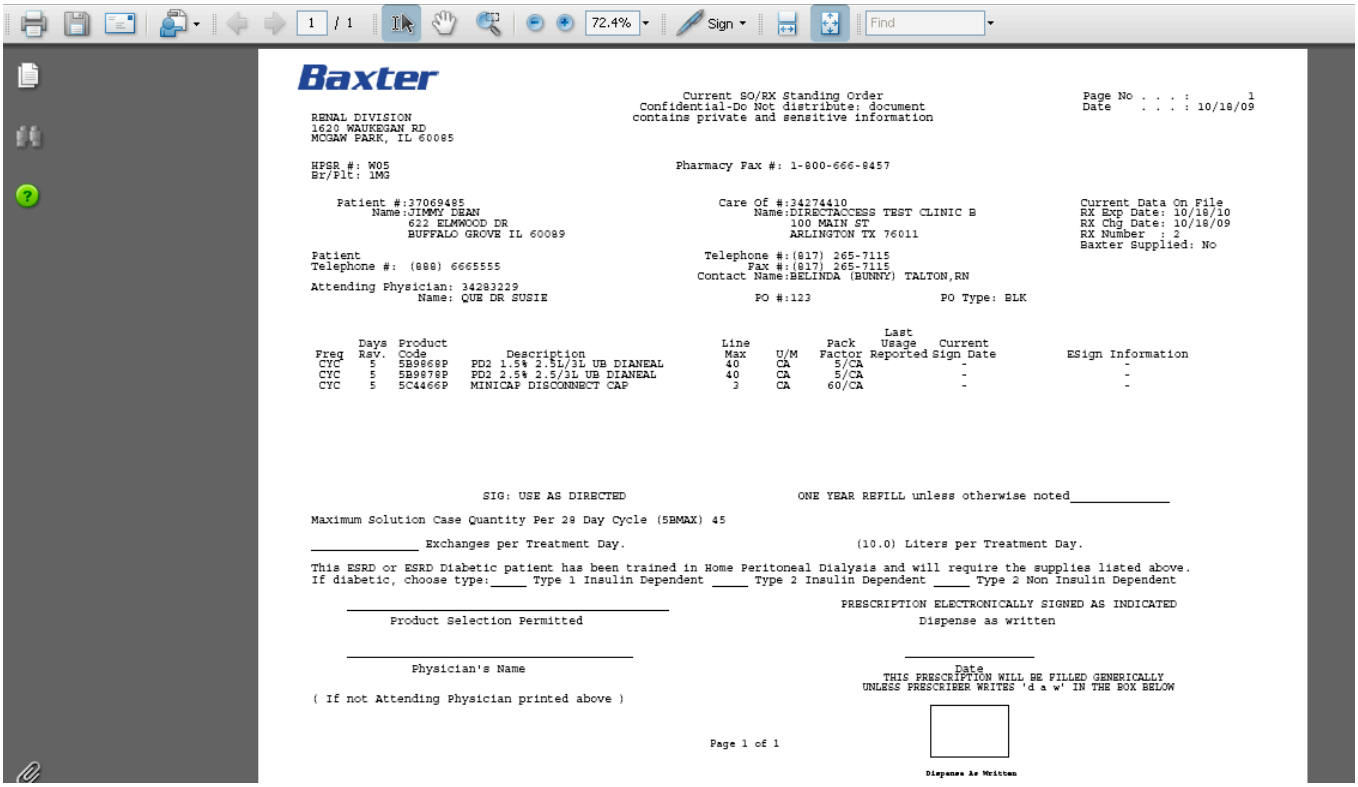


Example

2. Use the tabs on this screen to view or update the prescription. For additional information, please see the *Pending Patients User Guide*.

VIEW/PRINT PRESCRIPTION

1. To view or print the prescription, from the prescriptions box in the **To Do** list, click the **View/Print Rx** for that patient; the system displays a separate window with a PDF of the prescription.



Baxter

Current SO/RX Standing Order
Confidential-Do Not distribute: document
contains private and sensitive information

Page No . . . . : 1
Date . . . . : 10/16/09

RENAL DIVISION
1620 WAUKEGAN RD
MCGAW PARK, IL 60085

HPSR #: W05
Br/Plt: 1MG

Pharmacy Fax #: 1-800-666-8457

Patient #:37069485
Name:JIMMY DEAN
622 ELMWOOD DR
BUFFALO GROVE IL 60089

Patient
Telephone #: (888) 6665555

Attending Physician: 34283229
Name: QUE DR SUSIE

Care Of #:34274410
Name:DIRECTACCESS TEST CLINIC B
100 MAIN ST
ARLINGTON TX 76011

Telephone #:(817) 265-7115
Fax #:(817) 265-7115
Contact Name:BELINDA (BUNNY) TALTON,RN

PO #:123 PO Type: BLK

Current Data On File
RX Exp Date: 10/16/10
RX Chg Date: 10/16/09
RX Number : 2
Baxter Supplied: No

Freq	Days Rev.	Product Code	Description	Line Max	U/M	Pack Factor	Last Usage Reported	Current Sign Date	ESign Information
CYC	5	5B9868P	PD2 1.5% 2.5L/3L UB DIANEAL	40	CA	5/CA		-	-
CYC	5	5B9878P	PD2 2.5% 2.5/3L UB DIANEAL	40	CA	5/CA		-	-
CYC	5	5C4466P	MINICAP DISCONNECT CAP	3	CA	60/CA		-	-

SIG: USE AS DIRECTED ONE YEAR REFILL unless otherwise noted_____

Maximum Solution Case Quantity Per 28 Day Cycle (5BMAX) 45

_____ Exchanges per Treatment Day. (10.0) Liters per Treatment Day.

This ESRD or ESRD Diabetic patient has been trained in Home Peritoneal Dialysis and will require the supplies listed above.
If diabetic, choose type:____ Type 1 Insulin Dependent ____ Type 2 Insulin Dependent ____ Type 2 Non Insulin Dependent

_____
Product Selection Permitted

PRESCRIPTION ELECTRONICALLY SIGNED AS INDICATED
Dispense as written

_____
Physician's Name

_____
Date

(If not Attending Physician printed above)

THIS PRESCRIPTION WILL BE FILLED GENERICALLY
UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW

Page 1 of 1

Dispense As Written

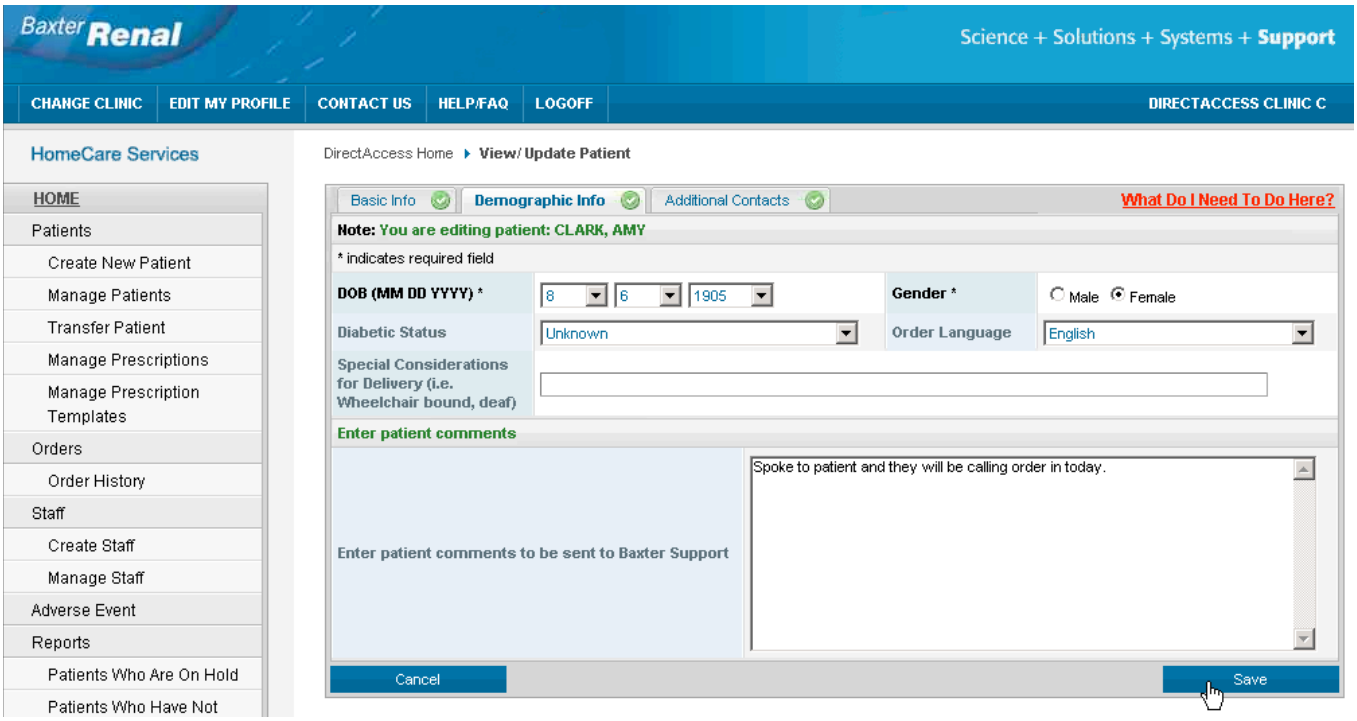
Example

2. Click on the Print icon at upper left to print the prescription.

3. Click **Home** to return to the **To Do** list.

SEND COMMENTS TO BAXTER

1. To send comments to Baxter concerning the prescription, from the prescriptions box in the **To Do** list, click the **Send Comments** link for that patient; the system displays the **Demographics Info** tab.



Example

2. Add comments as necessary and click **Save**; the system sends the comments to Baxter.

3. Click **Home** to return to the **To Do** list.

Annual Prescription Renewals

Baxter will not accept any order for patients without a prescription signed and dated by a physician.

The prescription **To Do** list also identifies prescriptions requiring a renewal.

Baxter Renal
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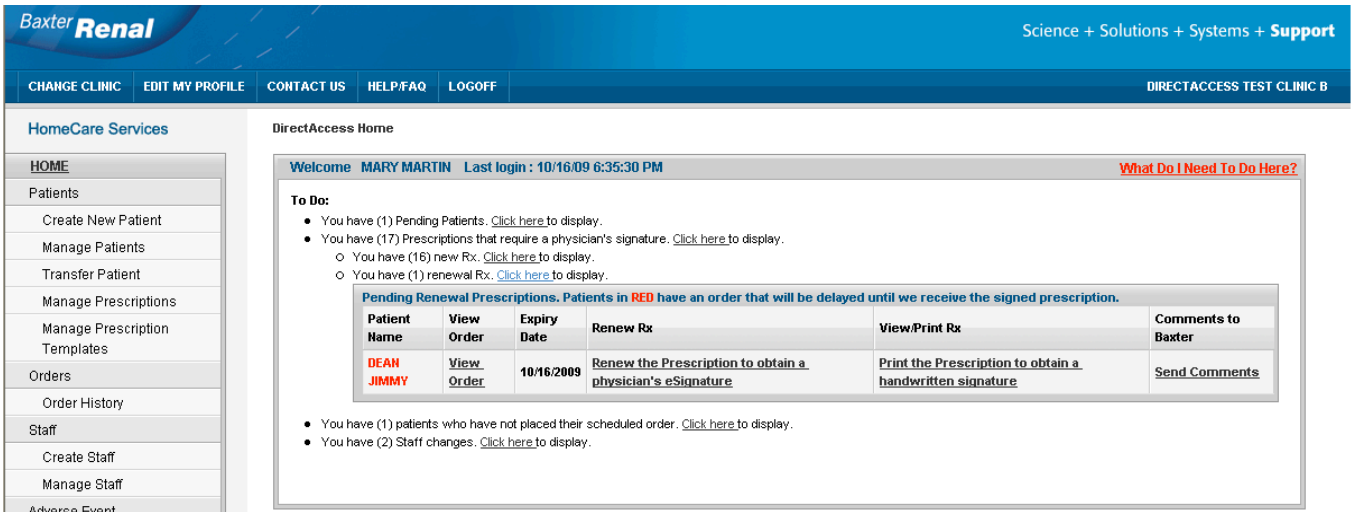
CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
DirectAccess Home
Welcome MARY MARTIN Last login : 10/14/09 11:45:42 AM
What Do I Need To Do Here?
To Do:
You have (2) Pending Patients. Click here to display.
You have (16) Prescriptions that require a physician's signature. Click here to display.
You have (14) new Rx. Click here to display.
You have (1) changed Rx. Click here to display.
You have (1) renewal Rx. Click here to display.

Example

1. Click the **Click Here** link on the **Renewal Rx** line to display the prescriptions requiring an annual renewal; the system displays the prescriptions in a box below the link you just clicked.


Baxter Renal
Science + Solutions + Systems + Support
CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Orders
Order History
Staff
Create Staff
Manage Staff
DirectAccess Home
Welcome MARY MARTIN Last login : 10/16/09 6:35:30 PM
What Do I Need To Do Here?
To Do:
You have (1) Pending Patients. Click here to display.
You have (17) Prescriptions that require a physician's signature. Click here to display.
You have (16) new Rx. Click here to display.
You have (1) renewal Rx. Click here to display.
Pending Renewal Prescriptions. Patients in RED have an order that will be delayed until we receive the signed prescription.
Patient Name
View Order
Expiry Date
Renew Rx
View/Print Rx
Comments to Baxter
DEAN JIMMY
View Order
10/16/2009
Renew the Prescription to obtain a physician's eSignature
Print the Prescription to obtain a handwritten signature
Send Comments
You have (1) patients who have not placed their scheduled order. Click here to display.
You have (2) Staff changes. Click here to display.

Example

Prescription renewals appear on the **To Do** list with the prescription expiration date noted. Patient names appearing in **Red** have an order that will be delayed until a signed prescription is received.

From this screen, you can:

- Renew the prescription to obtain a physician's eSignature
- Print the Prescription to obtain a handwritten signature

RENEW TO OBTAIN ESIGNATURE

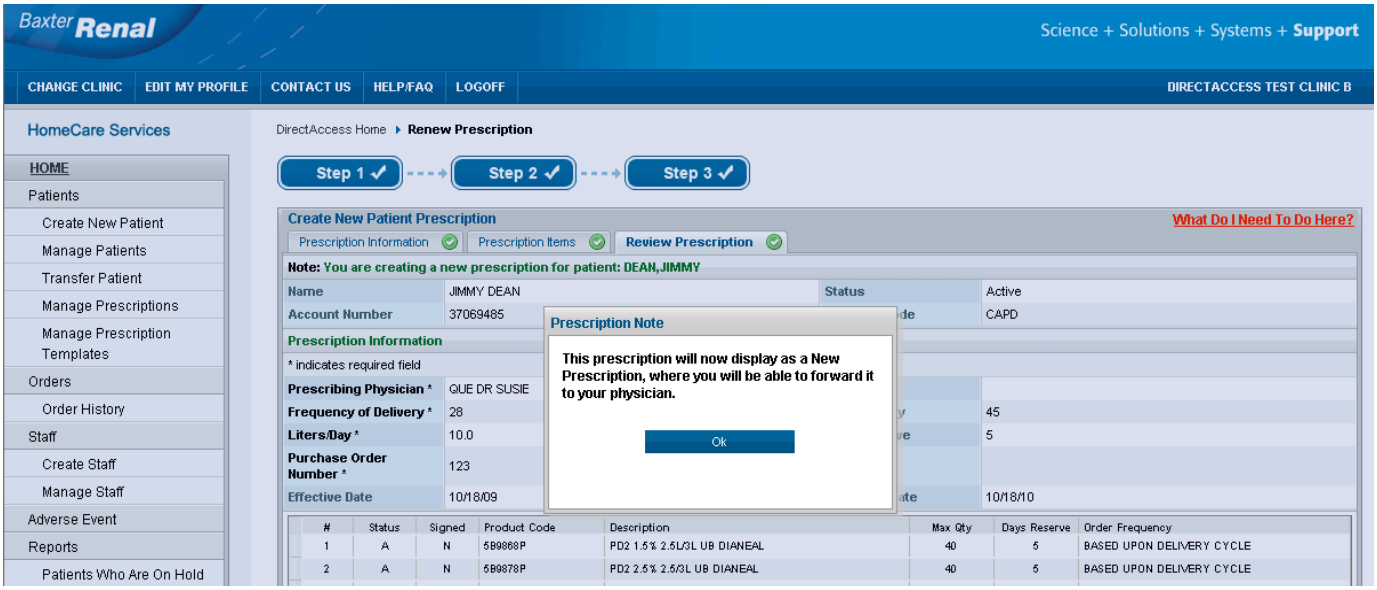
1. From the prescriptions box in the To Do list, click on **Renew the Prescription to obtain a physician's eSignature**; the system displays the **Renew Prescription** screen.

> This screen is just like the Create/Update Prescription screen. Use the tabs on this screen to view or update the prescription. For additional information, please see the Pending Patients User Guide.

2. Review the prescription information on each of the tabs and make any changes, if necessary. Reviewing and saving a prescription requiring renewal creates the new prescription.

3. When you are done, click **Save**.

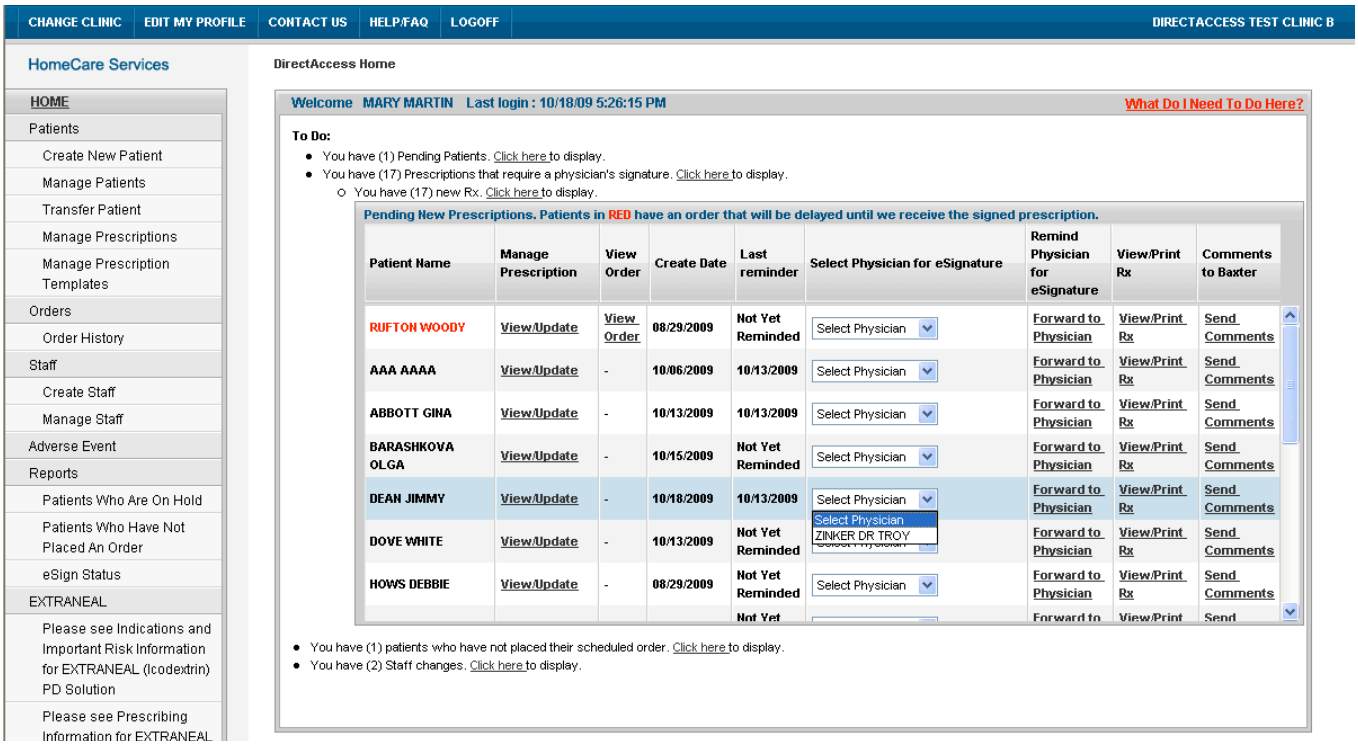
4. A **Prescription Note** appears, telling you that the prescription will now display as a New Prescription, where you will be able to forward it to your physician. Click **Ok**.



Example

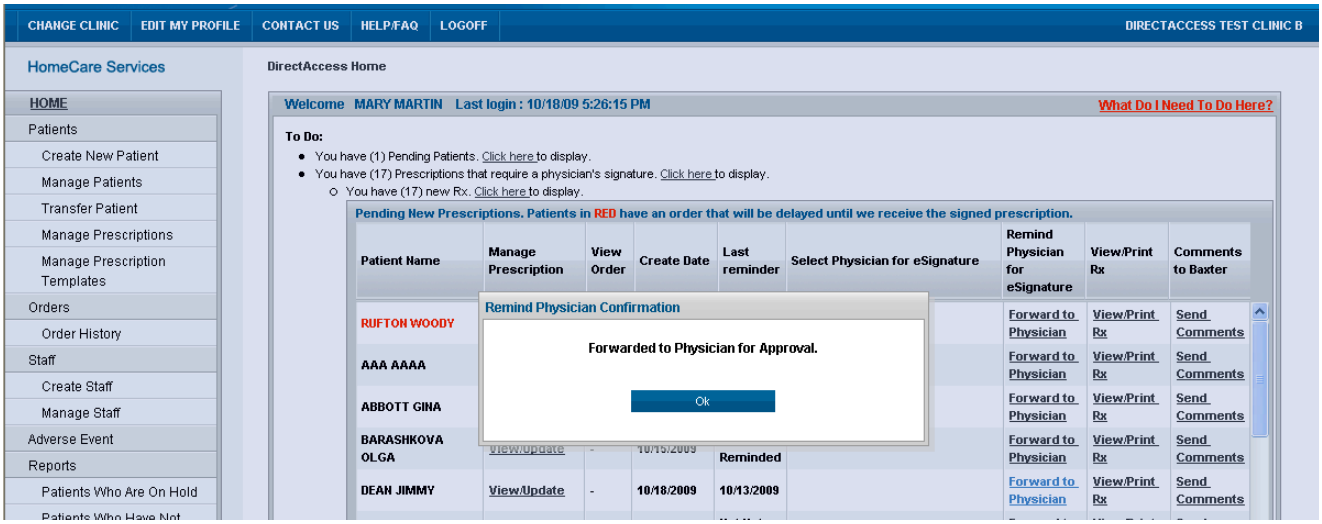
5. The system also asks if you wish to save the prescription as a template so you can use it as a starting point for other prescriptions. Click **Yes** to save as template. Click **No** to return to the **Home** screen.

6. The prescription you just renewed will now appear in the **new Rx To Do** list. Click the **Click here** on the **new Rx line** to display the list.



Example

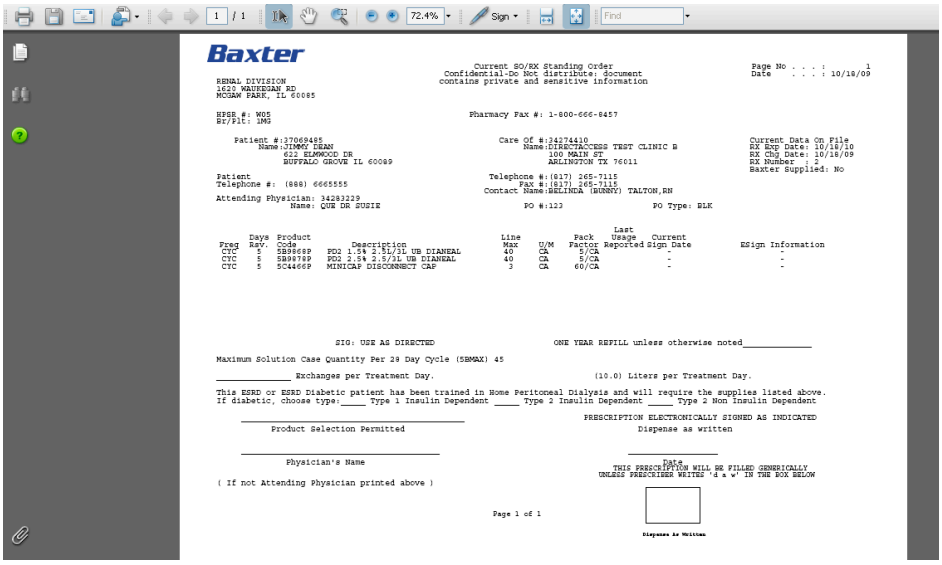
7. Find the prescription and use the **Select Physician for eSignatue** drop-down to select the physician. Click on the **Forward to Physician** link to forward the prescription to the physician for eSignature. The system displays the **Remind Physician Confirmation** message. Click **Ok**.



Example

TO PRINT PRESCRIPTION FOR YOUR FILES

1. Click the **Print the Prescription** link in the **To Do** list box for renewals; the system displays separate window with a PDF of the prescription.



Baxter

Current SO/RX Standing Order
Confidential-Do Not distribute; document contains private and sensitive information

Page No . . . . : 1
Date . . . . : 10/19/09

RENAL DIVISION
1620 WAUKEGAN RD
MCGAW PARK, IL 60085

HPSE #: W05
Rr/Plt: IMG

Pharmacy Fax #: 1-800-666-8457

Patient #:37069485
Name:JIMMY DEAN
622 ELMWOOD DR
BUFFALO GROVE IL 60089

Care Of #:34274410
Name:DIRECTACCESS TEST CLINIC B
100 MAIN ST
ARLINGTON TX 76011

Current Data On File
RX Exp Date: 10/18/10
RX Chg Date: 10/16/09
RX Number : 2
Baxter Supplied: No

Patient
Telephone #: (888) 6665555

Telephone #:(817) 265-7115
Fax #:(817) 265-7115
Contact Name:BELINDA (BUNNY) TALTON,RN

Attending Physician: 34283229
Name: QUE DR SUSIE

PO #:122 PO Type: BLK

Freq	Days Rev.	Product Code	Description	Line Max	U/M	Pack Factor	Last Usage Reported	Current RSign Date	RSign Information
CYC	5	5B9868P	PD2 1.5% 2.5L/3L UB DIANEAL	40	CA	5/CA	-	-	-
CYC	5	5B9879P	PD2 2.5% 2.5/3L UB DIANEAL	40	CA	5/CA	-	-	-
CYC	5	5C4466P	MINICAP DISCONNECT CAP	3	CA	60/CA	-	-	-

SIG: USE AS DIRECTED ONE YEAR REFILL unless otherwise noted_____

Maximum Solution Case Quantity Per 28 Day Cycle (5BMAX) 45

_____ Exchanges per Treatment Day. (10.0) Liters per Treatment Day.

This ESRD or ESRD Diabetic patient has been trained in Home Peritoneal Dialysis and will require the supplies listed above.
If diabetic, choose type:_____ Type 1 Insulin Dependent _____ Type 2 Insulin Dependent _____ Type 2 Non Insulin Dependent

_____ PRESCRIPTION ELECTRONICALLY SIGNED AS INDICATED
Product Selection Permitted Dispense as written

_____ _____
Physician's Name Date

(If not Attending Physician printed above)

THIS PRESCRIPTION WILL BE FILLED GENERICALLY
UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW

Page 1 of 1

Dispense As Written

Example

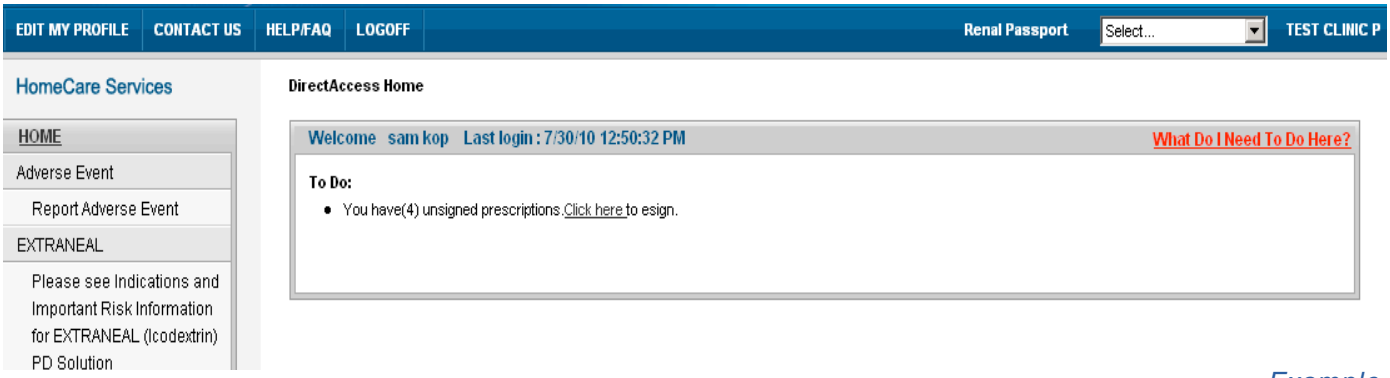
2. Click on the **Print** icon at upper left to print the prescription. Prescription renewals print with the current expiration date.

HomeCare Services

eSigning Prescriptions

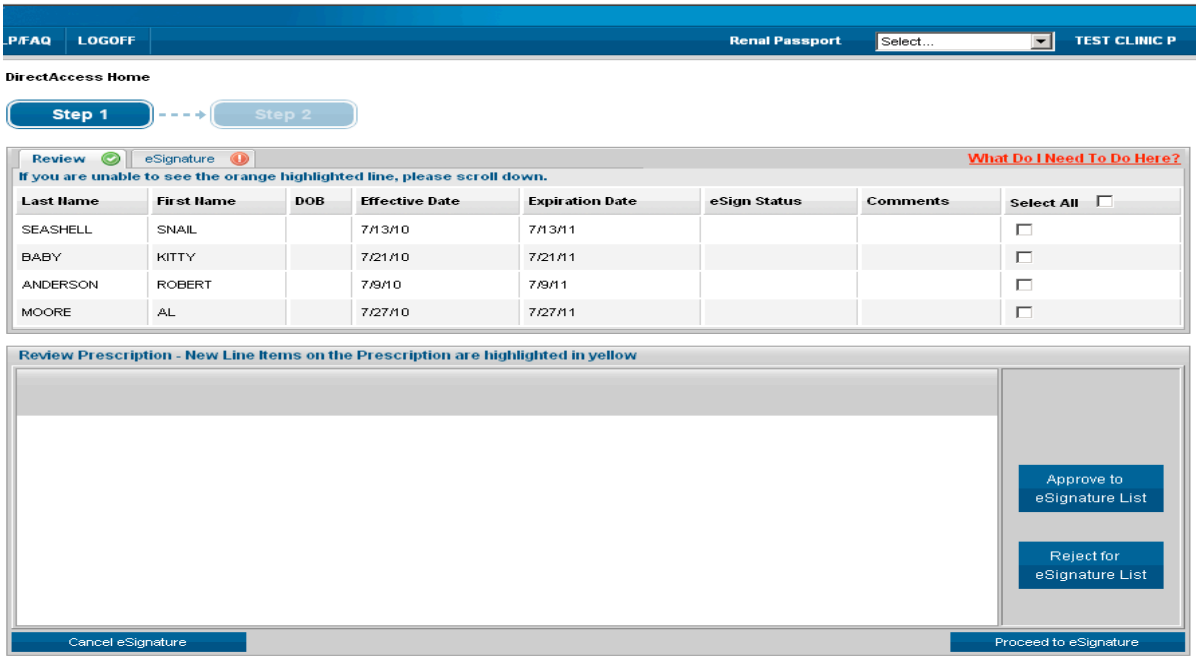
The Following Steps Will Guide You With eSigning.

1. Log in to the **DirectAccess** online tool. The Home page displays the To Do List. Click on the **Click here** link to view prescriptions that need to be reviewed and signed.



Example

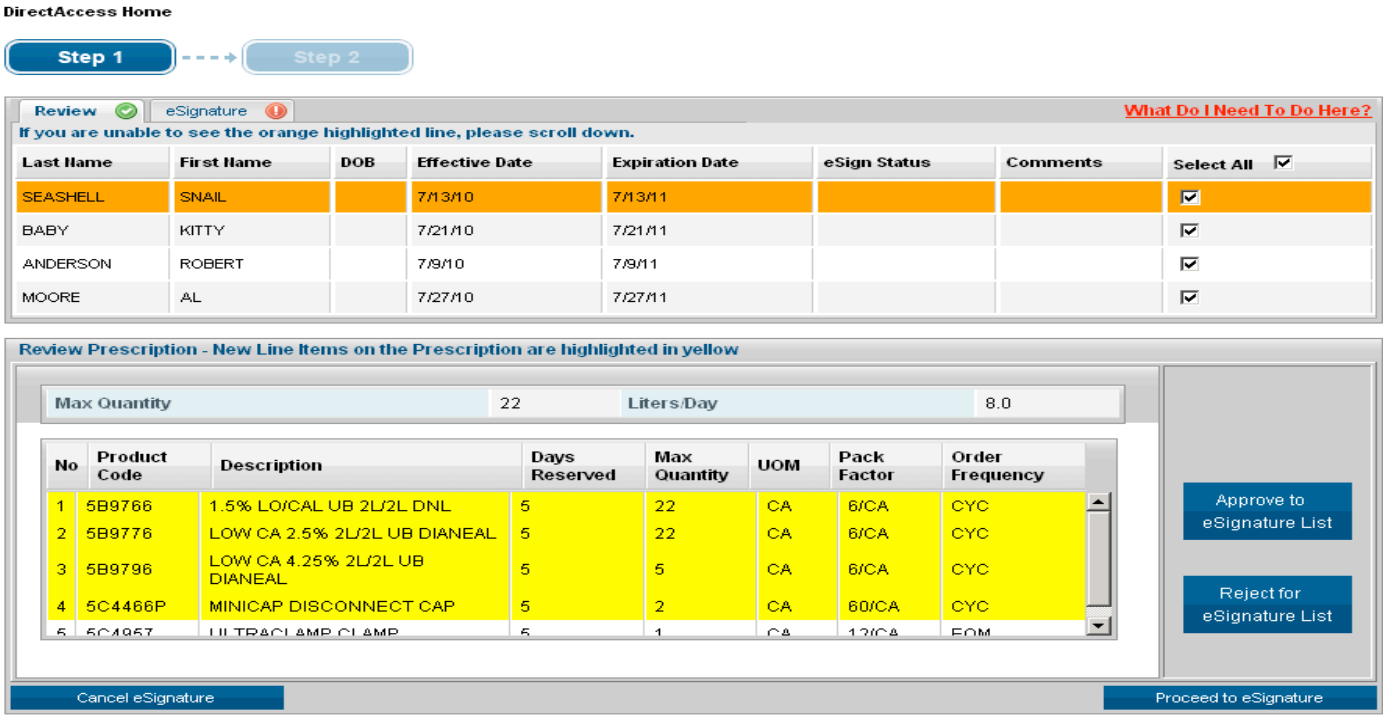
There are two tabs when signing a prescription electronically. The **Review** tab displays the patient information. You can view all of the prescriptions by clicking on **Select All** or click on only the ones you want to review.



Example

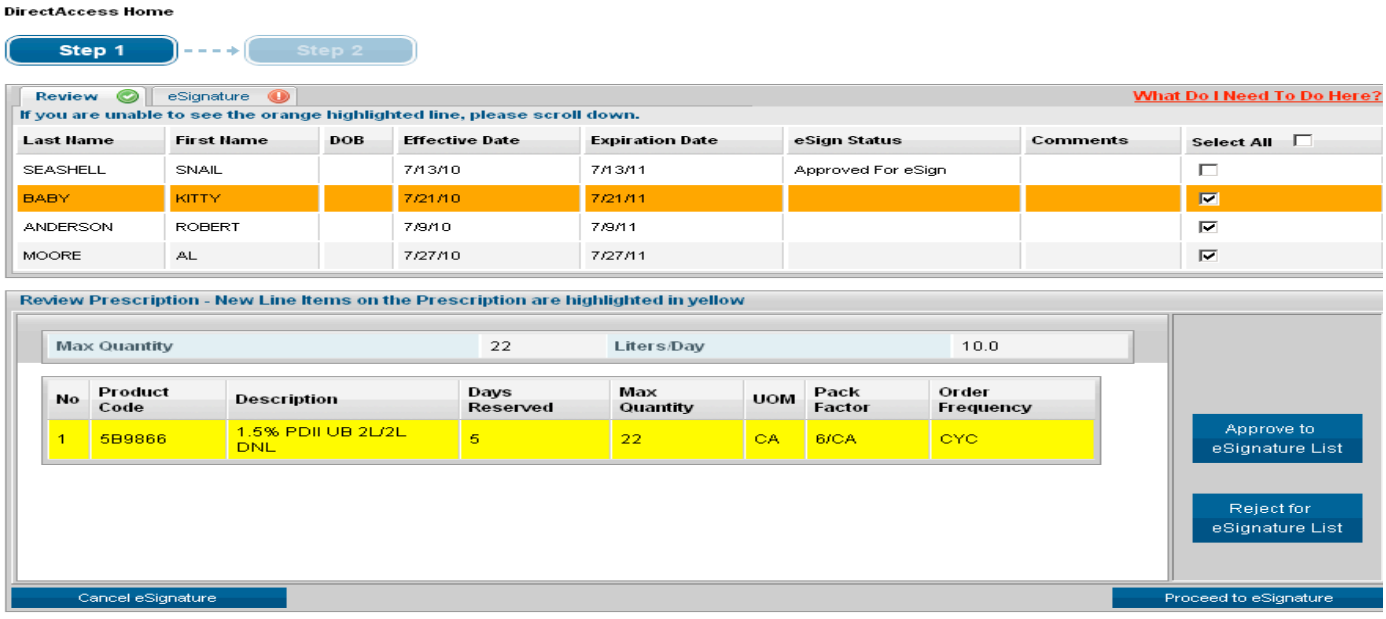
Click on **What Do I Need To Do Here** for additional help. This help option is located on each tab.

2. As each prescription is being reviewed, the patient's name will be highlighted in orange. The prescription items will display in the **Review Prescription** window. The items highlighted in yellow indicate they need a physician signature. After reviewing the prescription, click on **Approve to eSignature List.** To cancel the process at anytime, click on **Cancel eSignature**.



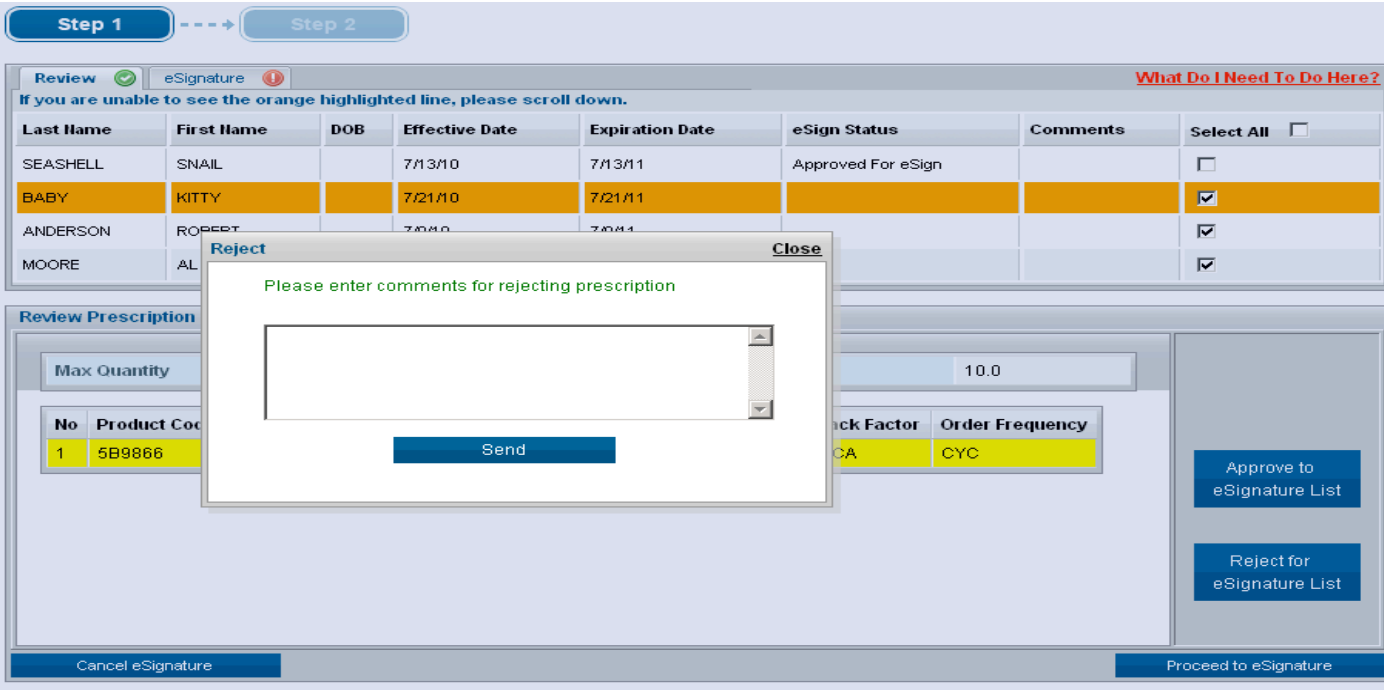
Example

3. When **Approve to eSignature** is selected, the next prescription displays. To reject a presciption, click on **Reject for eSignature List**.



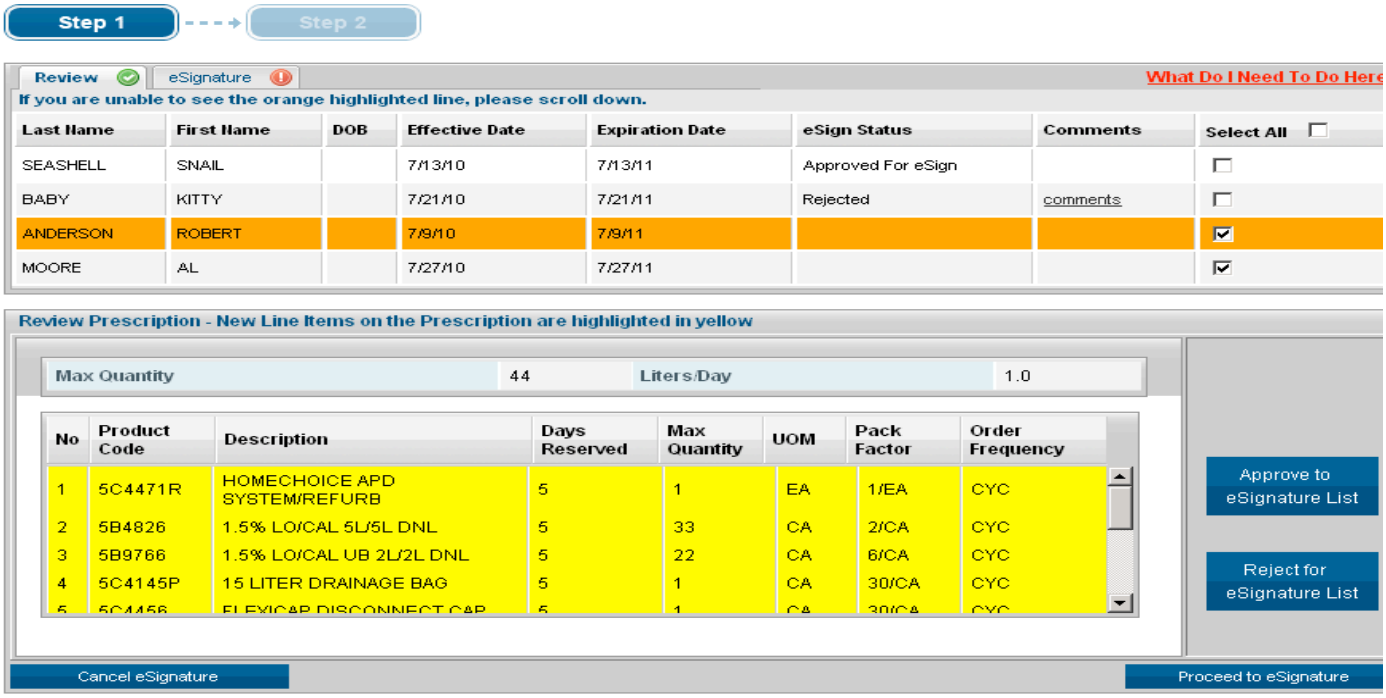
Example

4. When **Reject for eSignature List** is selected, comments will be required. These comments will display on the Site Administrators **eSign Status** report for further follow up. After entering the comments, click **Send**.



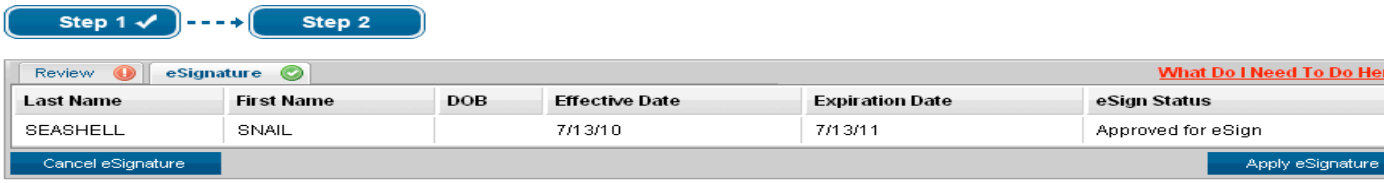
Example

5. Once prescriptions have been reviewed, the current status is displayed in the **eSign Status** column. In the **Comments** column, it's indicated that comments were entered for the rejected prescription. To apply the eSignature to prescriptions **Approved for eSign**, click on **Proceed to eSignature**.



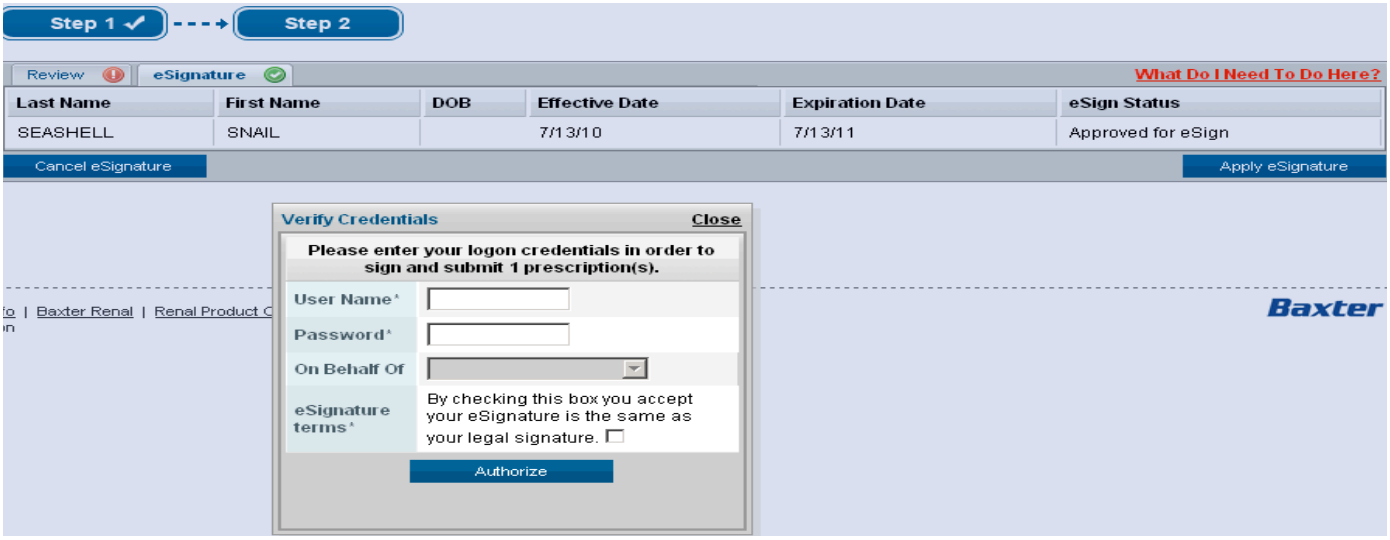
Example

6. The **eSignature** tab displays with the prescription(s) that are approved for eSignature. Click on **Apply eSignature**.



Example

7. The **Verify Credentials** window displays. Enter the **User Name** and **Password** that was used to log in to **DirectAccess** online tool. Physician Assistants and Nurse Practitioners will be required to select a physician from the **On Behalf Of** drop down box. Click the **eSignature terms** check box and click **Authorize**.



Example

8. The **Batch eSign** confirmation window displays. Click **Close** to return to the **Home** page.

Example

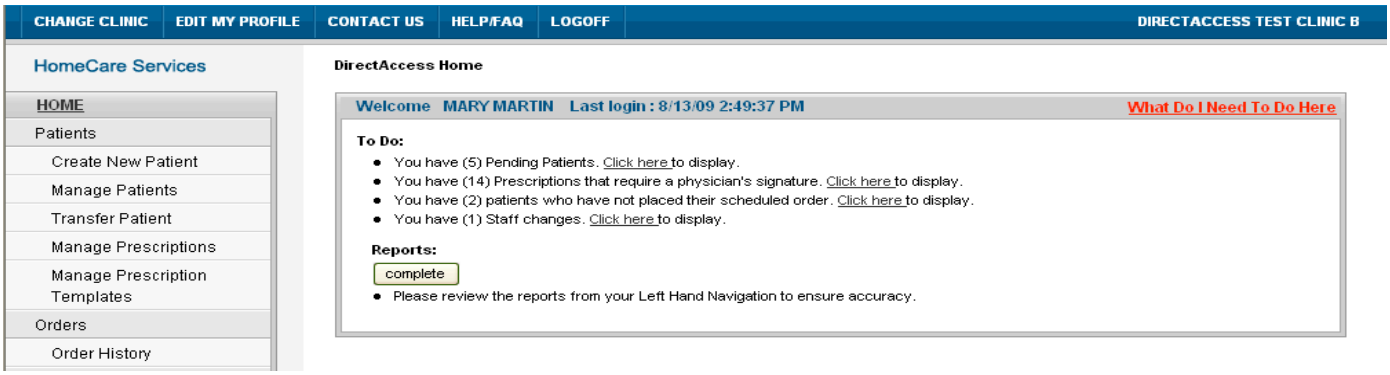
HomeCare Services

Scheduled Orders

Scheduled Orders

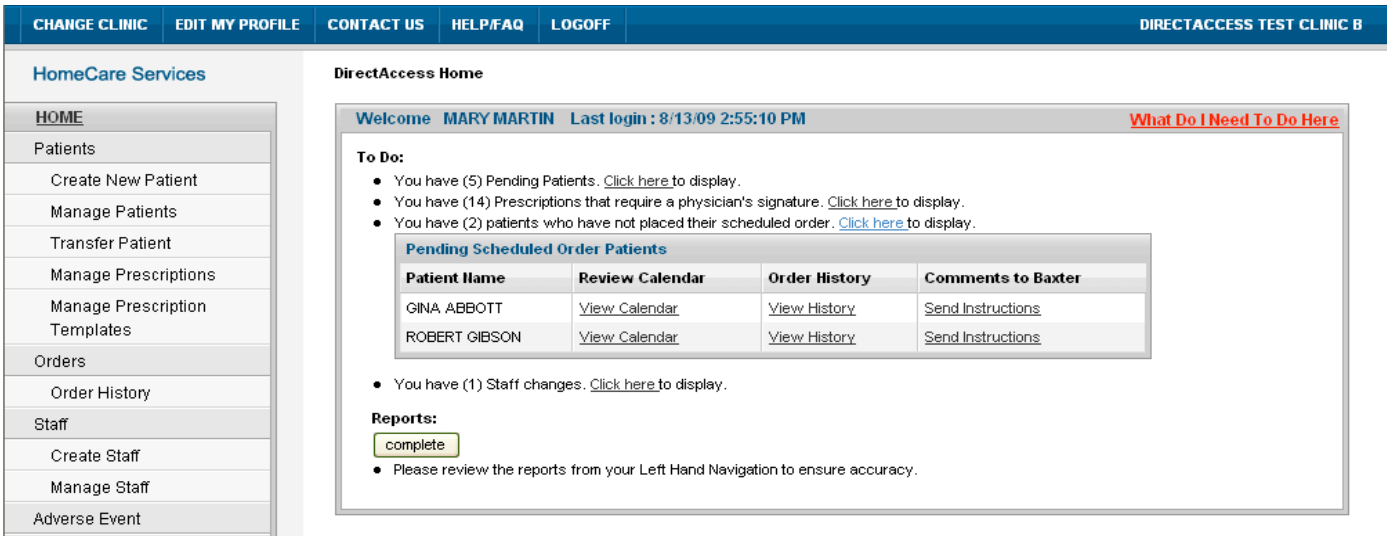
After logging on, the system displays the **DirectAccess** online tool Home Page. An item on the **To Do** list identifies the patients who have not placed their scheduled orders.

For each patient, the system enables you to easily view that patient's calendar, look at their order history, and send a comment to Baxter if needed.


CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Orders
Order History
DirectAccess Home
Welcome MARY MARTIN Last login : 8/13/09 2:49:37 PM
What Do I Need To Do Here
To Do:
You have (5) Pending Patients. Click here to display.
You have (14) Prescriptions that require a physician's signature. Click here to display.
You have (2) patients who have not placed their scheduled order. Click here to display.
You have (1) Staff changes. Click here to display.
Reports:
complete
Please review the reports from your Left Hand Navigation to ensure accuracy.

Example

1. To see a list of these patients, click the **Click Here** link to display; the system displays **Pending Scheduled Order Patients** in a box below the link you just clicked.

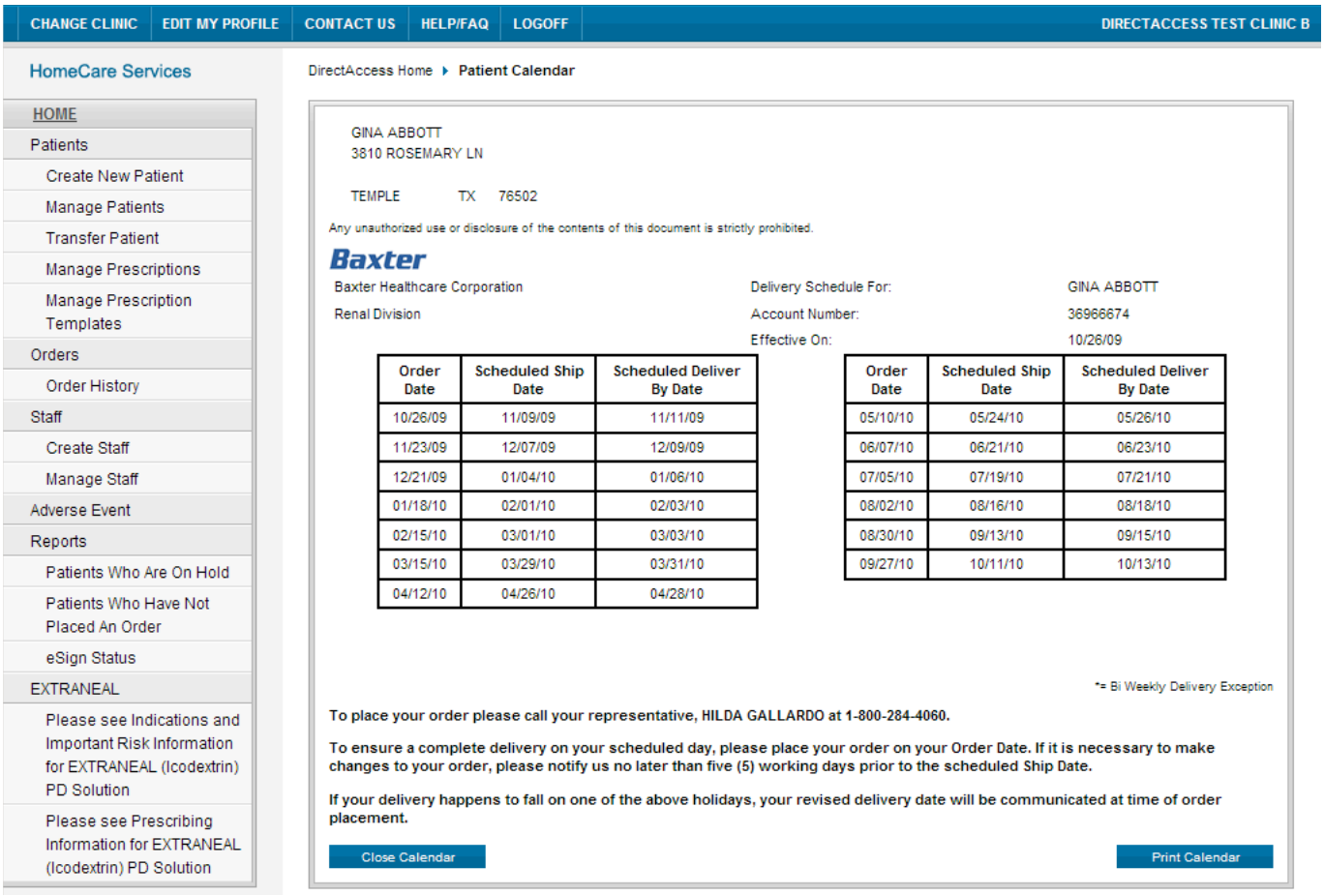


Example

2. You can then use the system to view the patient's calendar, look at order history, or send a comment to Baxter by clicking on the appropriate link for that patient.

VIEW CALENDAR

1. To view a patient's calendar, click on the **View Calendar** link for that patient; the system displays the calendar.


CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Orders
Order History
Staff
Create Staff
Manage Staff
Adverse Event
Reports
Patients Who Are On Hold
Patients Who Have Not Placed An Order
eSign Status
EXTRANEAL
Please see Indications and Important Risk Information for EXTRANEAL (Icodextrin) PD Solution
Please see Prescribing Information for EXTRANEAL (Icodextrin) PD Solution
DirectAccess Home
Patient Calendar
GINA ABBOTT
3810 ROSEMARY LN
TEMPLE TX 76502
Any unauthorized use or disclosure of the contents of this document is strictly prohibited.
Baxter
Baxter Healthcare Corporation
Renal Division
Delivery Schedule For: GINA ABBOTT
Account Number: 36966674
Effective On: 10/26/09
Order Date | Scheduled Ship Date | Scheduled Deliver By Date
10/26/09 | 11/09/09 | 11/11/09
11/23/09 | 12/07/09 | 12/09/09
12/21/09 | 01/04/10 | 01/06/10
01/18/10 | 02/01/10 | 02/03/10
02/15/10 | 03/01/10 | 03/03/10
03/15/10 | 03/29/10 | 03/31/10
04/12/10 | 04/26/10 | 04/28/10
Order Date | Scheduled Ship Date | Scheduled Deliver By Date
05/10/10 | 05/24/10 | 05/26/10
06/07/10 | 06/21/10 | 06/23/10
07/05/10 | 07/19/10 | 07/21/10
08/02/10 | 08/16/10 | 08/18/10
08/30/10 | 09/13/10 | 09/15/10
09/27/10 | 10/11/10 | 10/13/10
*= Bi Weekly Delivery Exception
To place your order please call your representative, HILDA GALLARDO at 1-800-284-4060.
To ensure a complete delivery on your scheduled day, please place your order on your Order Date. If it is necessary to make changes to your order, please notify us no later than five (5) working days prior to the scheduled Ship Date.
If your delivery happens to fall on one of the above holidays, your revised delivery date will be communicated at time of order placement.
Close Calendar
Print Calendar

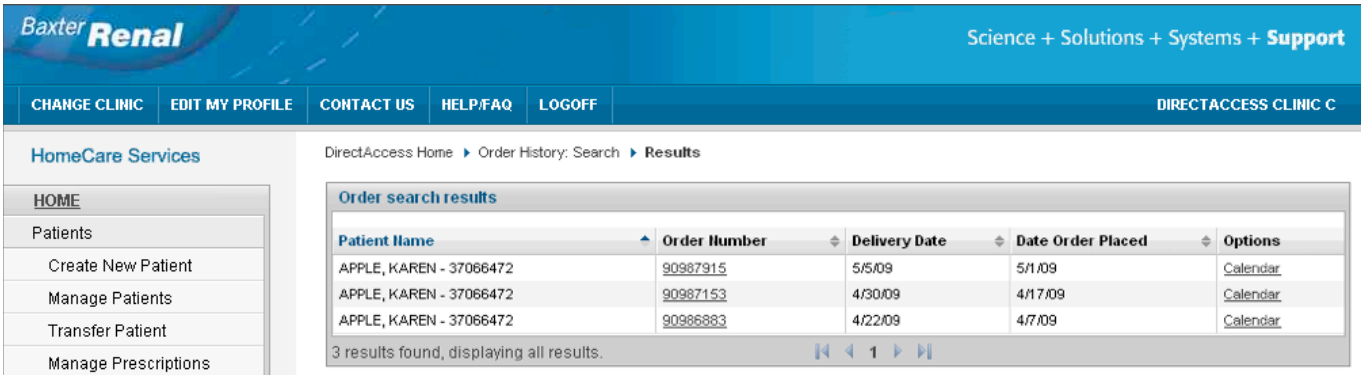
Example

2. Click **Print Calendar** to print calendar as needed.

3. To return to the To Do list, click **Home** from the left navigation bar.

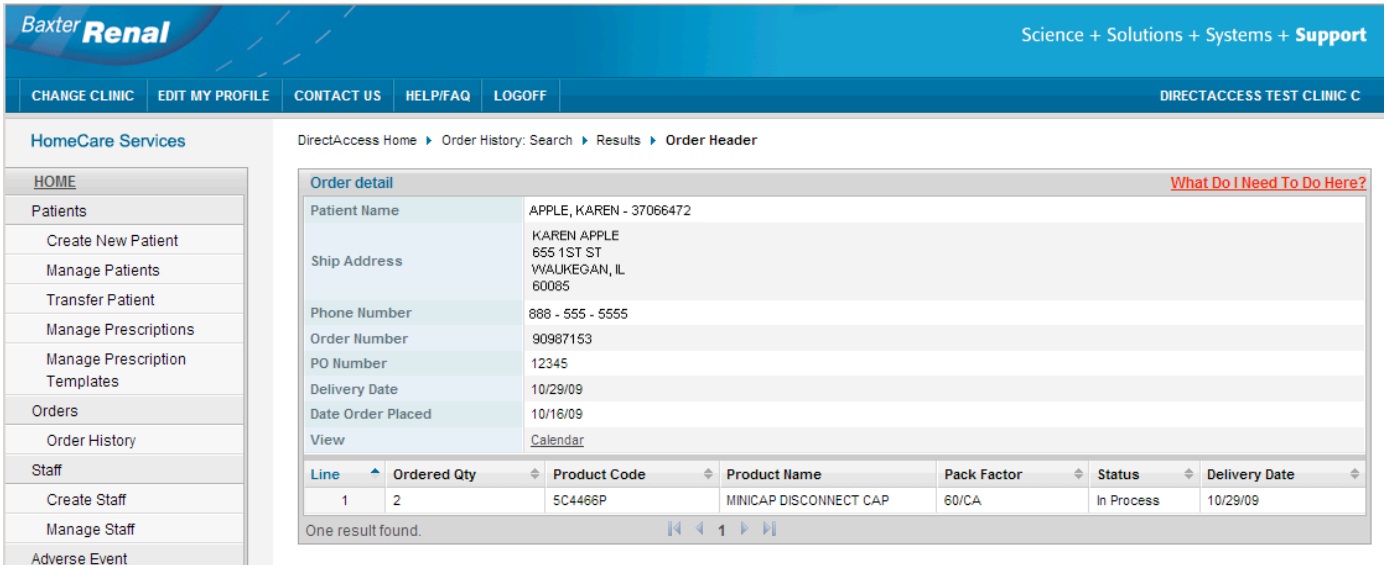
VIEW HISTORY

1. To view a patient's order history, return to the **To Do List** and click to display the **Pending Scheduled Order Patients** box. Click the **View History** link for the patient; the system displays the **Order Search Results** window with the patient's orders listed.



Example

2. Select the desired order and click on the **Order Number** to View the order. The system displays the Order Detail with the Shipping Address, Order Quantity, Product Code, Product Name, Pack Factor, Status, and Delivery Date.

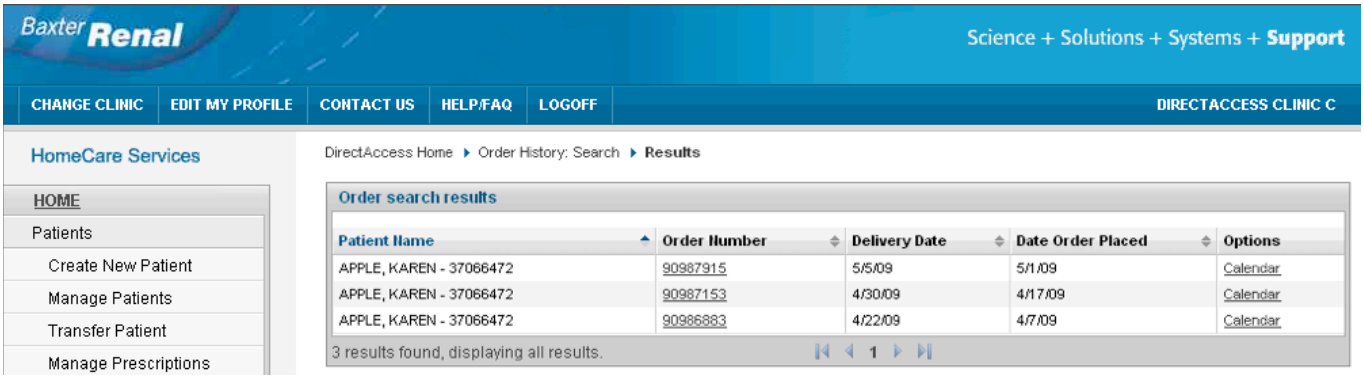


Example

3. To return to the To Do list, click **Home** from the left navigation bar.

SEND COMMENTS

1. To send comments, return to the **To Do** list and click to display the **Pending Scheduled Order Patients** box. Click the **Send Instructions** link for the patient; the system displays the **Demographics Info** tab.



Example

2. Add comments as necessary and click **Save**; the system sends the comments to Baxter.

3. To return to the To Do list, click **Home** from the left navigation bar.

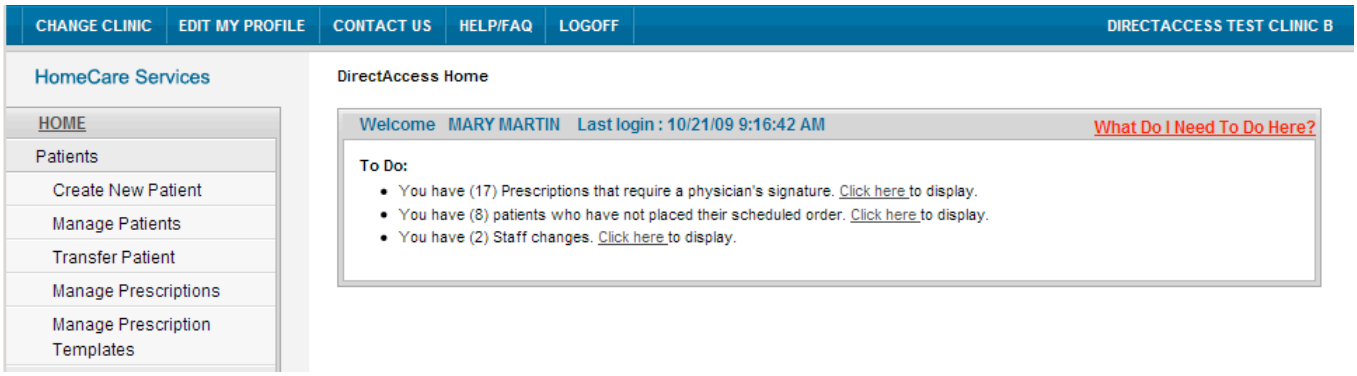
HomeCare Services

Patient On Hold

Patient Status Change: How To Put a Patient On Hold

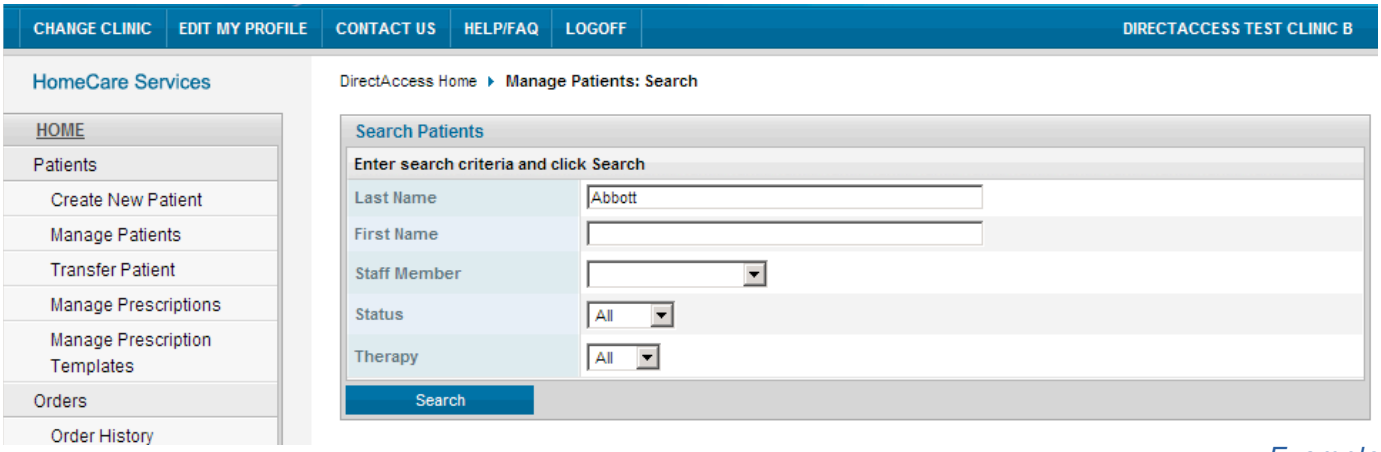
The following steps will guide you through putting a patient on hold.

After logging on, the system displays the **DirectAccess** online tool Home Page.


CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
DirectAccess Home
Welcome MARY MARTIN Last login : 10/21/09 9:16:42 AM
What Do I Need To Do Here?
To Do:
You have (17) Prescriptions that require a physician's signature. Click here to display.
You have (8) patients who have not placed their scheduled order. Click here to display.
You have (2) Staff changes. Click here to display.

Example

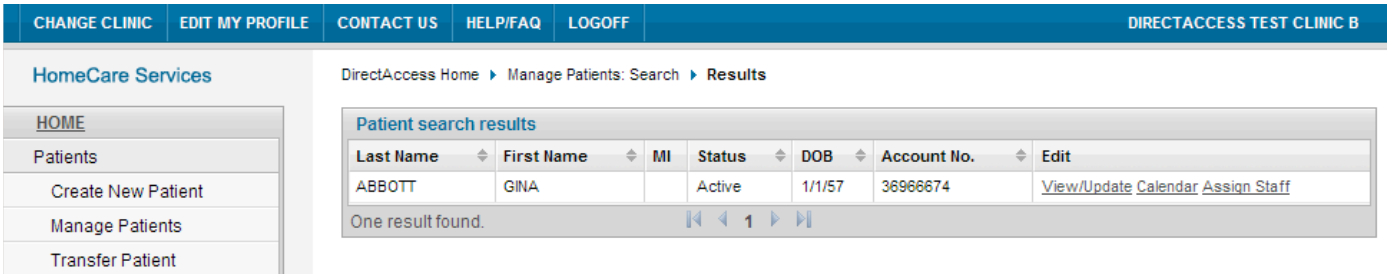
1. In the navigation bar on the left, click **Manage Patients**; the system displays the **Search Patients** screen.



Example

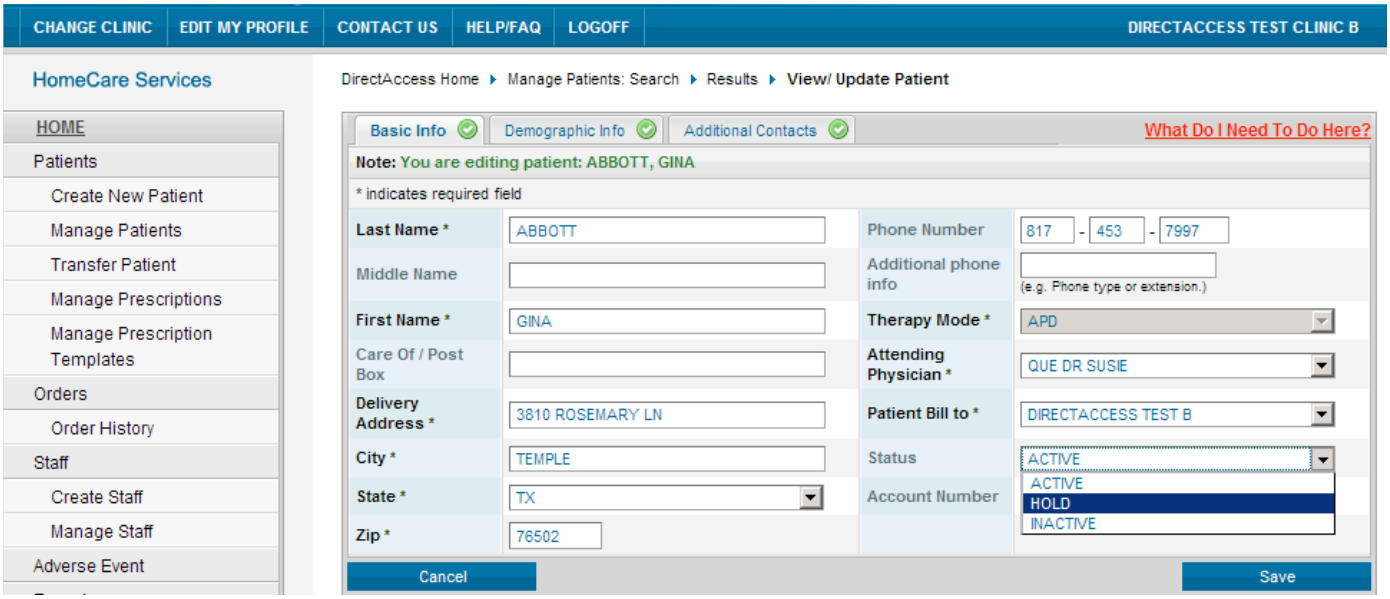
2. Enter the patient's last name, make sure **All** is selected in the Status drop-down, and click **Search**.

The system displays the **Patient Search Results** screen.



Example

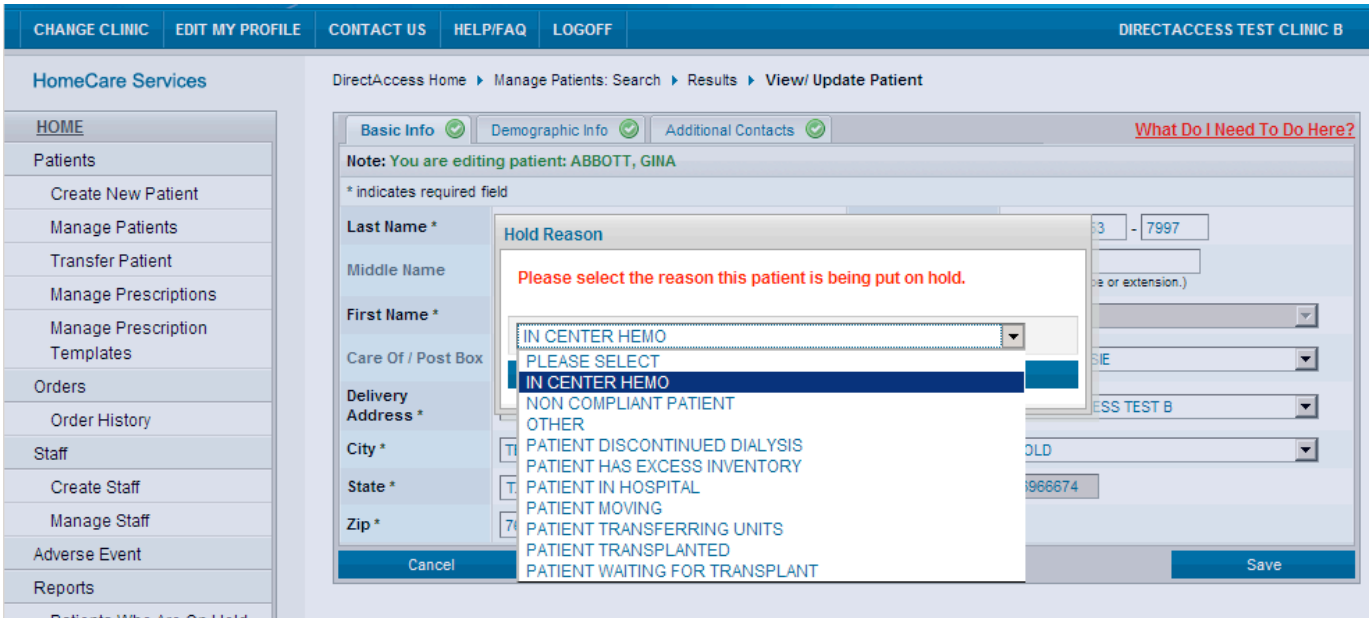
3. Click the **View/Update** link; the system displays the **Basic Info** tab of the **View/Update Patient** screen. The note indicates the name of the patient you are editing.



Example

4. Select **Hold** from the **Status** drop-down and click **Save**.

The system displays the **Hold Reason** dialog.



Example

5. Select the appropriate **Hold Reason** from the list and click **Save**. The system confirms the save; click **Ok**.

   The patient's status has been changed.

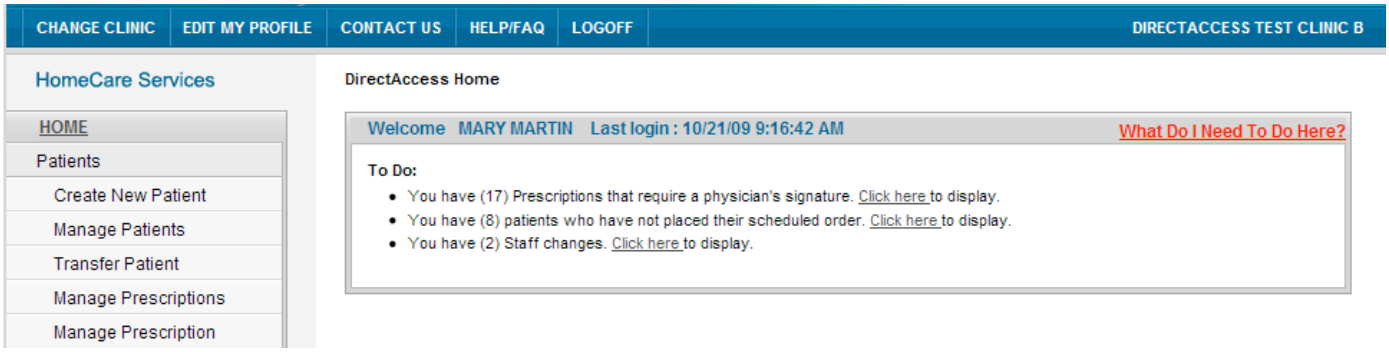
HomeCare Services

Inactivate A Patient

Patient Status Change: How To Inactivate a Patient

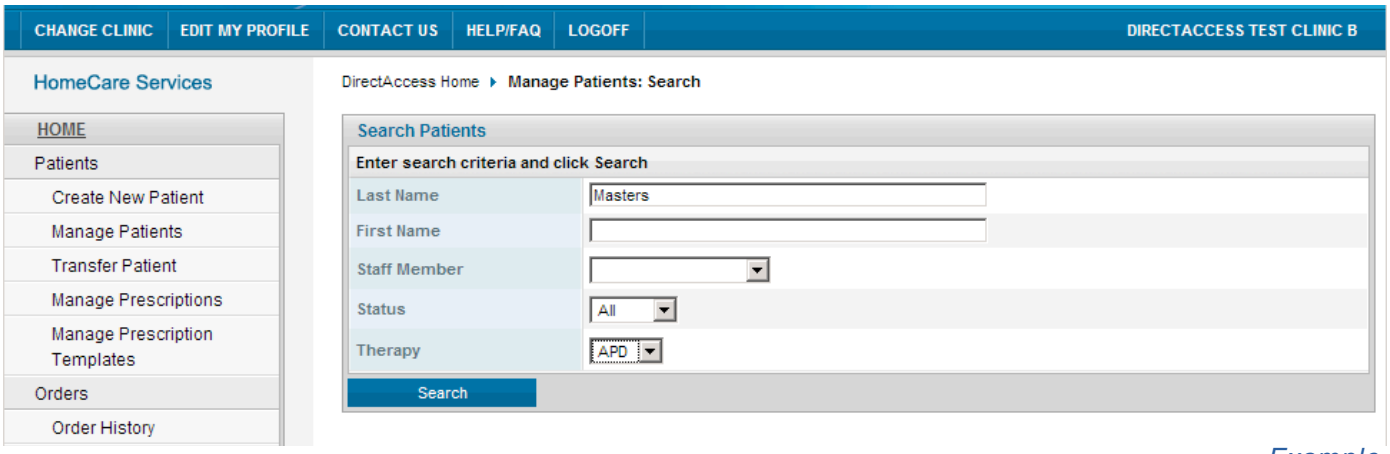
The following steps will guide you in changing a patient's status from an **Active** or **Hold** status to **Inactive**.

After logging on, the system displays the **DirectAccess** online tool Home Page.


CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription
DirectAccess Home
Welcome MARY MARTIN Last login : 10/21/09 9:16:42 AM
What Do I Need To Do Here?
To Do:
You have (17) Prescriptions that require a physician's signature. Click here to display.
You have (8) patients who have not placed their scheduled order. Click here to display.
You have (2) Staff changes. Click here to display.

Example

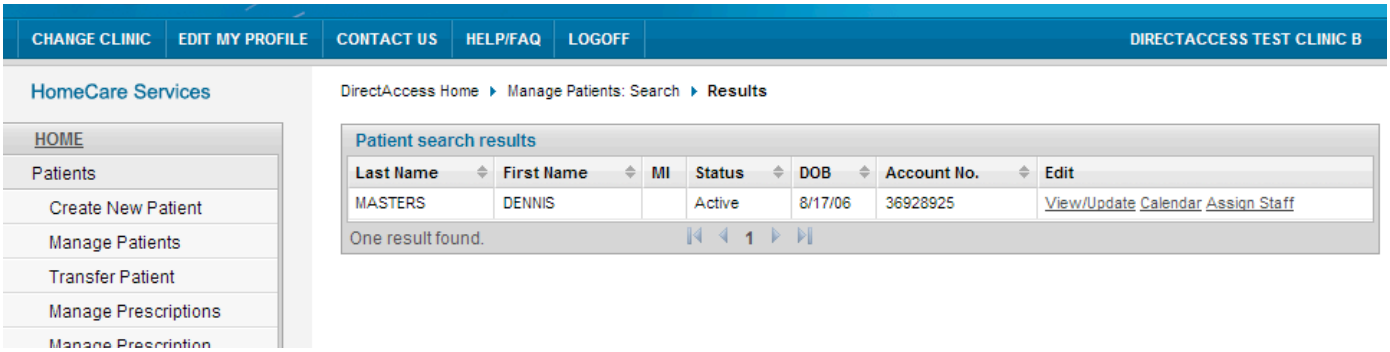
1. In the navigation bar on the left, click **Manage Patients**; the system displays the **Search Patients** screen.



Example

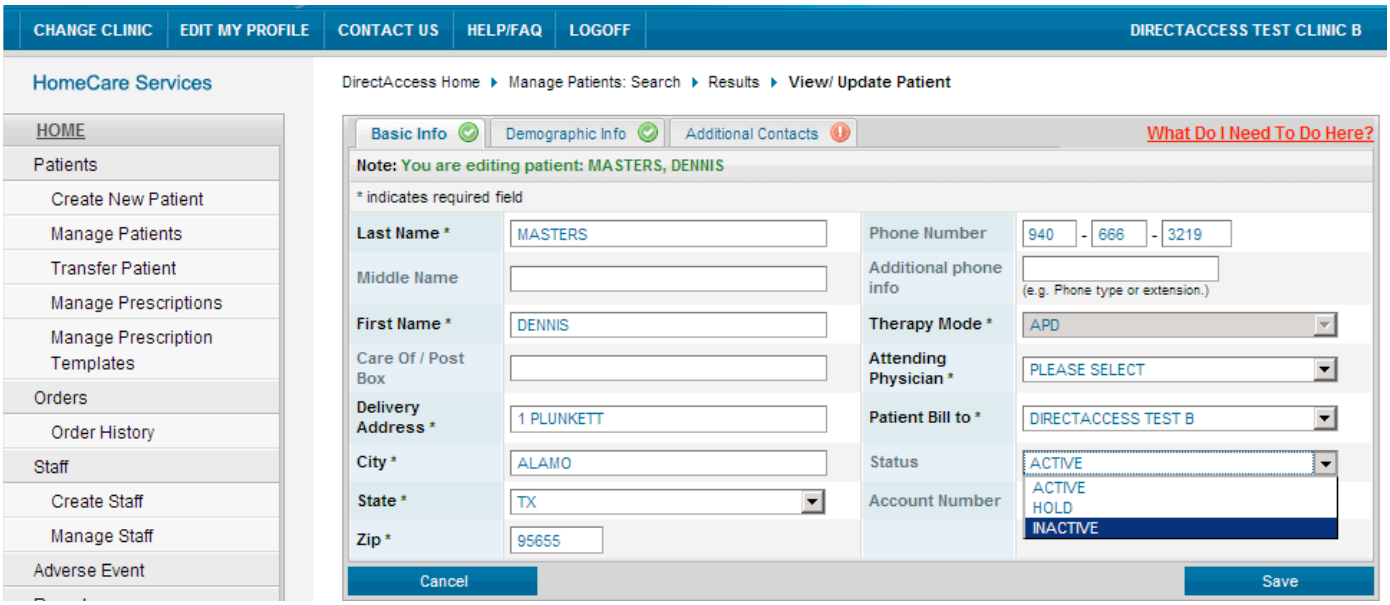
2. Enter the patient's last name, make sure **All** is selected in the **Status** drop-down, and select the patient's therapy from the **Therapy** drop-down. Click **Search**.

The system displays the **Patient Search Results** screen.



Example

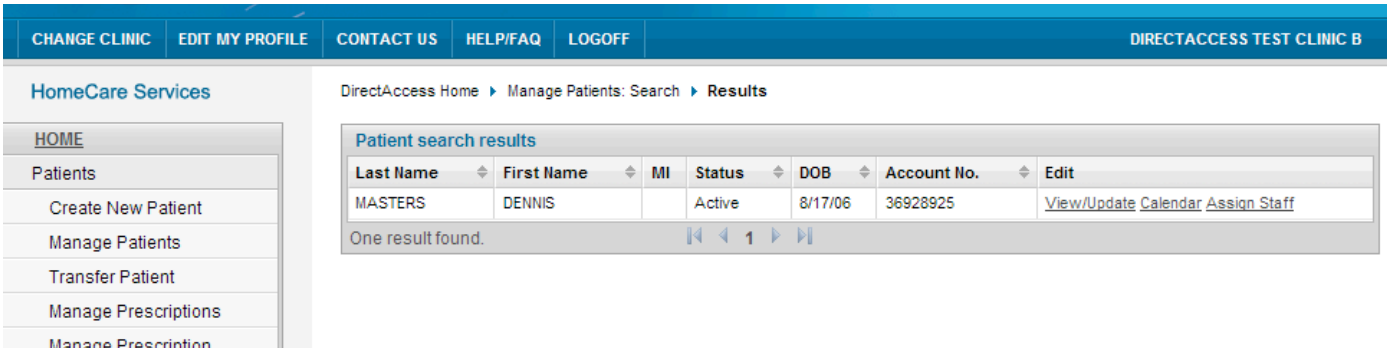
3. Click the **View/Update** link; the system displays the **Basic Info** tab of the **View/Update Patient** screen. The note indicates the name of the patient you are inactivating.



Example

4. Select **Inactive** from the **Status** drop-down and click **Save**.

The system displays the **Loss Reason** dialog.



Example

5. Select the appropriate **Loss Reason** from the list and click **Save**. The system confirms the change; click **Ok**.

UNSIGNED PRESCRIPTION

> In the situation where the patient you are inactivating has an unsigned prescription, the system will not confirm the change.

Instead, the system displays the following message, which tells you that there are outstanding prescriptions for the patient and that all patient prescriptions must be signed before the patient can be inactivated.

Active Prescriptions
There are outstanding prescriptions for this patient. All patient prescriptions must be signed before this patient can be inactivated.
Ok

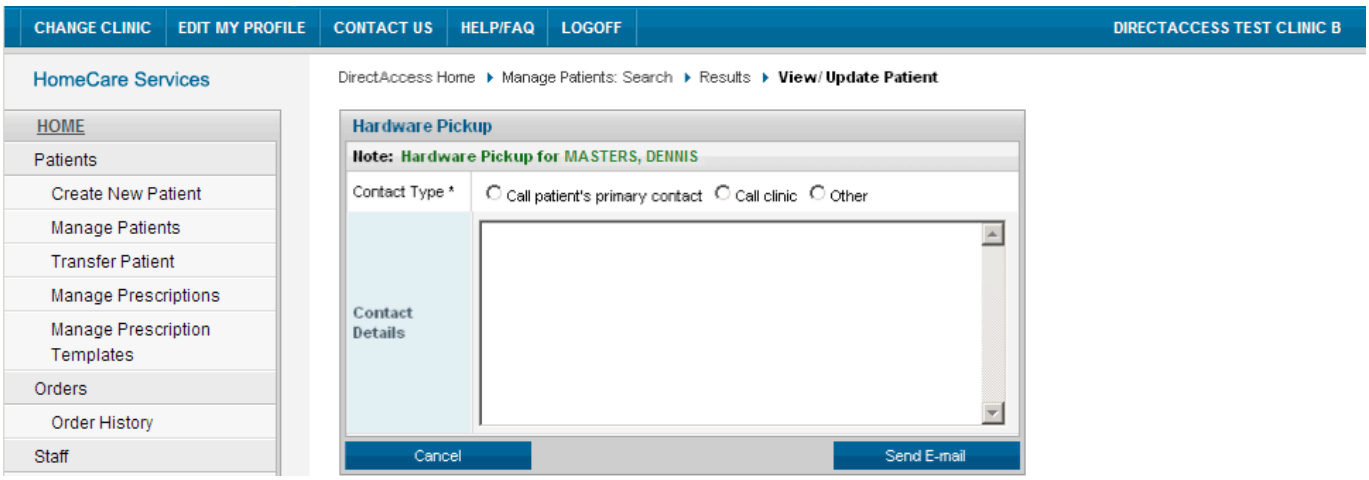
If you receive this message, click **Ok** and work your unsigned prescriptions from your **To Do** list.

AUTOMATED PERITONEAL DIALYSIS (APD) PATIENT

In the situation where the patient you are inactivating is an APD patient, the system will continue the process in order to manage the return of APD hardware and disposables.

APD PATIENT - HARDWARE PICKUP

The system displays the **Hardware Pickup** screen.



Example

1. Choose the **Contact Type** by clicking the radio button to identify who should be contacted to make arrangements for the pickup of the patient's cycler:

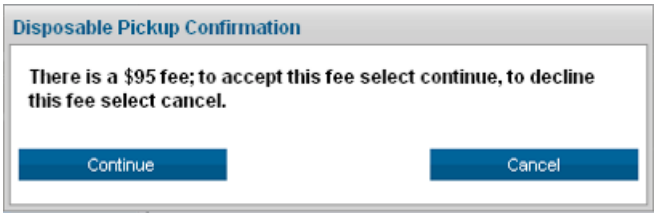
   - Selecting **Call patient's primary contact** indicates the primary phone number/contact provided to Baxter's HomeCare Services should be called
   - Selecting **Call clinic** indicates the cycler was brought to the dialysis unit and you'd like to be contacted for pickup arrangements
   - Selecting **Other** indicates you would like to make other arrangements. Use the text box to enter the appropriate information, such as contact name (e.g., in the event the patient is deceased) or alternate phone numbers (e.g., nursing home number, spouse/family cell phone numbers, etc.)

The text box can only be used when the **Other** radio button is selected.

2. If you are providing information in the **Contact Details** box, you do not need to provide an explanation or reason for the hardware pickup.

APD PATIENT - DISPOSABLES PICKUP

Next, the system displays the **Disposables Pickup Confirmation** dialog.


Disposable Pickup Confirmation
There is a $95 fee; to accept this fee select continue, to decline this fee select cancel.
Continue
Cancel

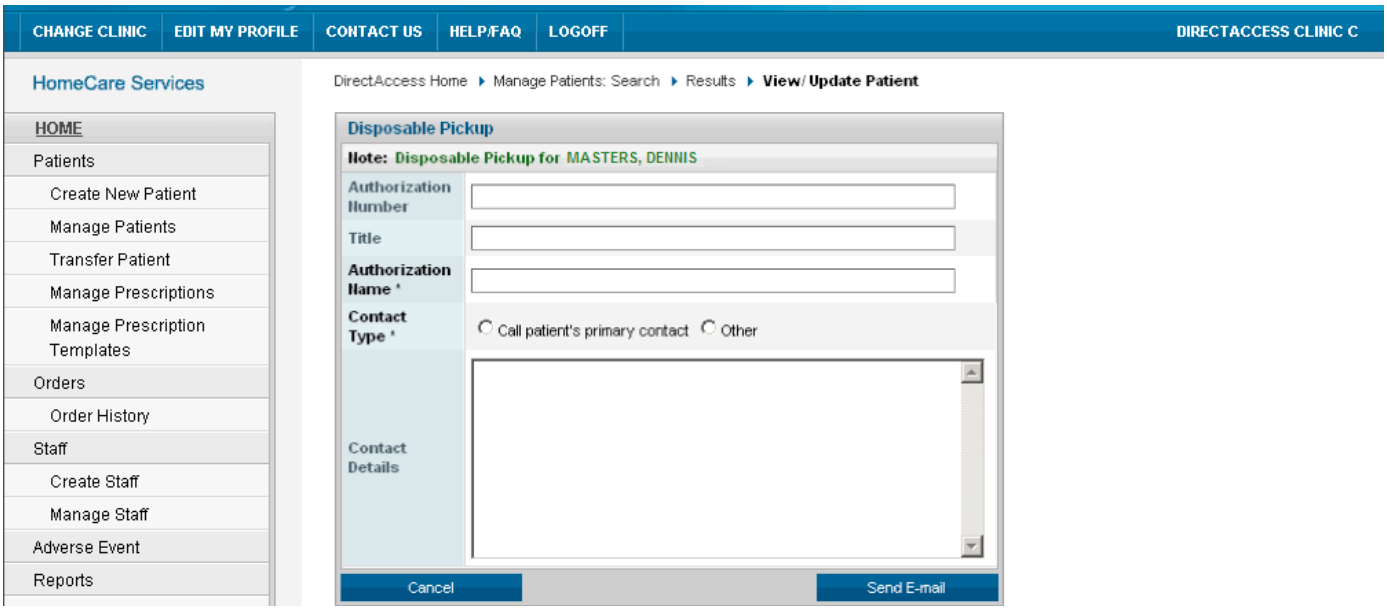
1. Click either Continue or Cancel:

    - By selecting **Continue**, you agree to the $95.00 pickup fee and request Baxter's HomeCare Services to contact the patient or family and make appropriate arrangements

    - By selecting **Cancel**, you tell the system that you've made prior arrangements with the patient to dispose of remaining disposable products

> If you click Cancel, no arrangements will be made by Baxter HomeCare Services.

If you click **Continue**, meaning that you agree to the $95.00 pickup fee and request Baxter's HomeCare Services to contact the patient or family and make appropriate arrangements, the system displays the Disposables Pickup screen.



Example

1. In the **Authorization Number** field (optional), enter an Authorization Number. This is used if your dialysis center requires an additional authorization.

2. In the **Title and Authorization Name** fields, enter the title and name of the person authorizing the $95.00 pickup fee. This may be authorized by any person/title at your dialysis center.

> Entering a person's name and title establishes that the person identified has authority to approve charges on the dialysis center's behalf.

3. Choose the **Contact Type** by clicking the radio button to identify who should be contacted to make arrangements for the pickup of the patient's disposables:

   - Selecting **Call patient's primary contact** indicates the primary phone number/contact provided to Baxter's HomeCare Services should be called
   - Selecting **Other** indicates you would like to make other arrangements. Use the text box to enter the appropriate information, such as contact name (e.g., in the event the patient is deceased) or alternate phone numbers (e.g., nursing home number, spouse/family cell phone numbers, etc.)

> The text box can only be used when the **Other** radio button is selected.

4. If you are providing information in the Contact Details box, you do not need to provide an explanation or reason for the disposables pickup.

5. Click **Ok**. The system confirms that your information has been successfully saved.

Click **Ok**.

Your inactivation is now complete

HomeCare Services

Modality Changes

Modality Changes

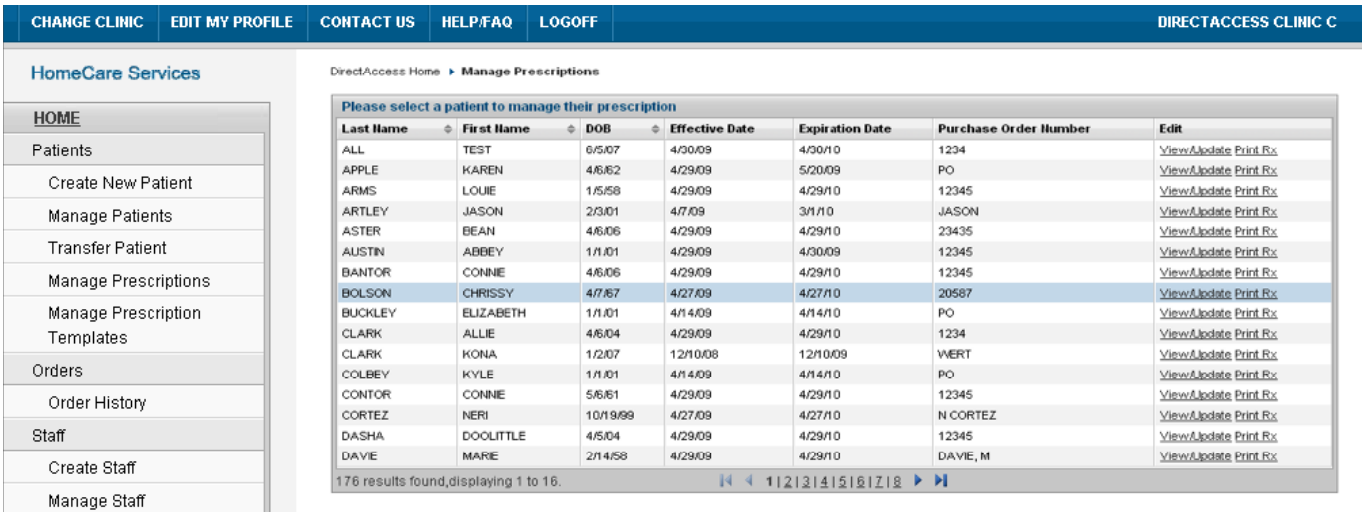
The following steps will guide you in changing a patient's therapy.

After logging on, the system displays the **DirectAccess** online tool Home Page.

CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Orders
DirectAccess Home
Welcome MARY MARTIN Last login : 10/13/09 5:52:49 PM
What Do I Need To Do Here?
To Do:
You have (2) Pending Patients. Click here to display.
You have (14) Prescriptions that require a physician's signature. Click here to display.
You have (1) patients who have not placed their scheduled order. Click here to display.
You have (2) Staff changes. Click here to display.

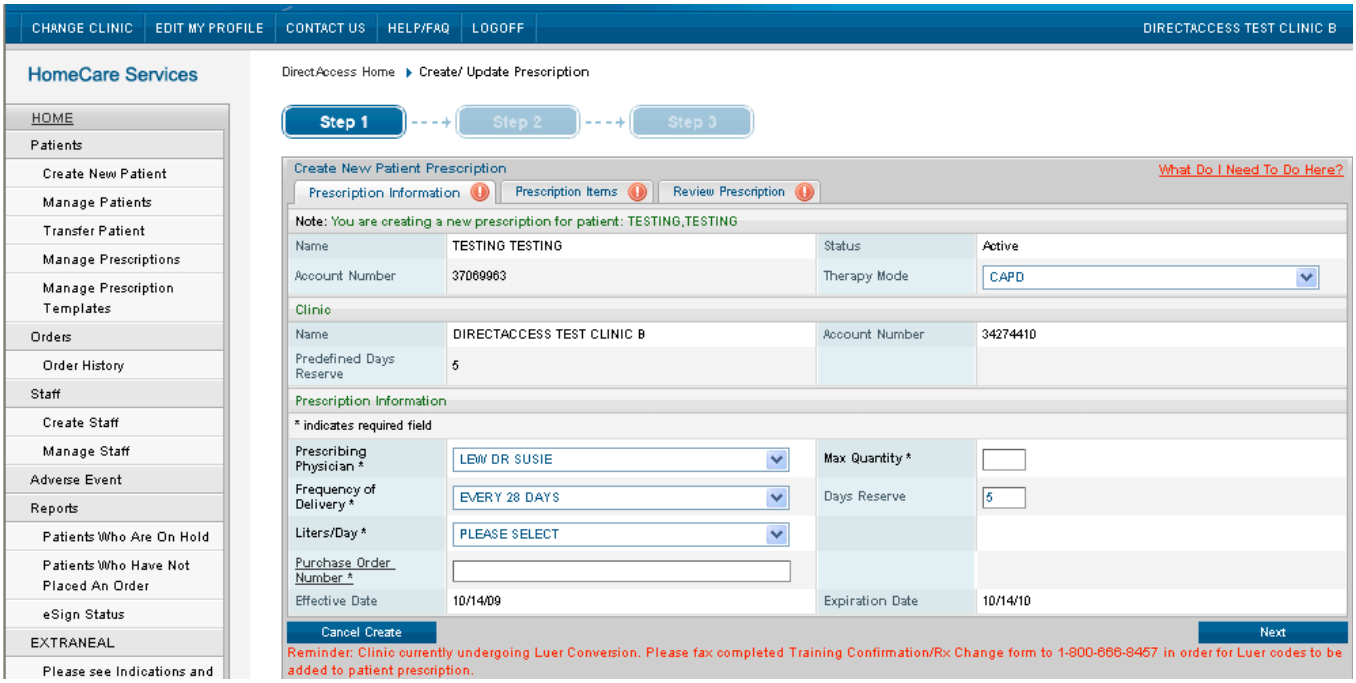
Example

1. In the navigation bar on the left, click **Manage Prescriptions**; the system displays the **Manage Prescriptions** screen with a patient listing.


CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS CLINIC C
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Orders
Order History
Staff
Create Staff
Manage Staff
DirectAccess Home ▸ Manage Prescriptions
Please select a patient to manage their prescription
Last Name | First Name | DOB | Effective Date | Expiration Date | Purchase Order Number | Edit
ALL | TEST | 6/5/07 | 4/30/09 | 4/30/10 | 1234 | View/Update Print Rx
APPLE | KAREN | 4/6/62 | 4/29/09 | 5/20/09 | PO | View/Update Print Rx
ARMS | LOUIE | 1/5/58 | 4/29/09 | 4/29/10 | 12345 | View/Update Print Rx
ARTLEY | JASON | 2/3/01 | 4/7/09 | 3/1/10 | JASON | View/Update Print Rx
ASTER | BEAN | 4/6/06 | 4/29/09 | 4/29/10 | 23435 | View/Update Print Rx
AUSTIN | ABBEY | 1/1/01 | 4/29/09 | 4/30/09 | 12345 | View/Update Print Rx
BANTOR | CONNIE | 4/6/06 | 4/29/09 | 4/29/10 | 12345 | View/Update Print Rx
BOLSON | CHRISSY | 4/7/67 | 4/27/09 | 4/27/10 | 20587 | View/Update Print Rx
BUCKLEY | ELIZABETH | 1/1/01 | 4/14/09 | 4/14/10 | PO | View/Update Print Rx
CLARK | ALLIE | 4/6/04 | 4/29/09 | 4/29/10 | 1234 | View/Update Print Rx
CLARK | KONA | 1/2/07 | 12/10/08 | 12/10/09 | WERT | View/Update Print Rx
COLBEY | KYLE | 1/1/01 | 4/14/09 | 4/14/10 | PO | View/Update Print Rx
CONTOR | CONNIE | 5/6/61 | 4/29/09 | 4/29/10 | 12345 | View/Update Print Rx
CORTEZ | NERI | 10/19/99 | 4/27/09 | 4/27/10 | N CORTEZ | View/Update Print Rx
DASHA | DOOLITTLE | 4/5/04 | 4/29/09 | 4/29/10 | 12345 | View/Update Print Rx
DAVIE | MARIE | 2/14/58 | 4/29/09 | 4/29/10 | DAVIE, M | View/Update Print Rx
176 results found,displaying 1 to 16.
1 | 2 | 3 | 4 | 5 | 6 | 7 | 8

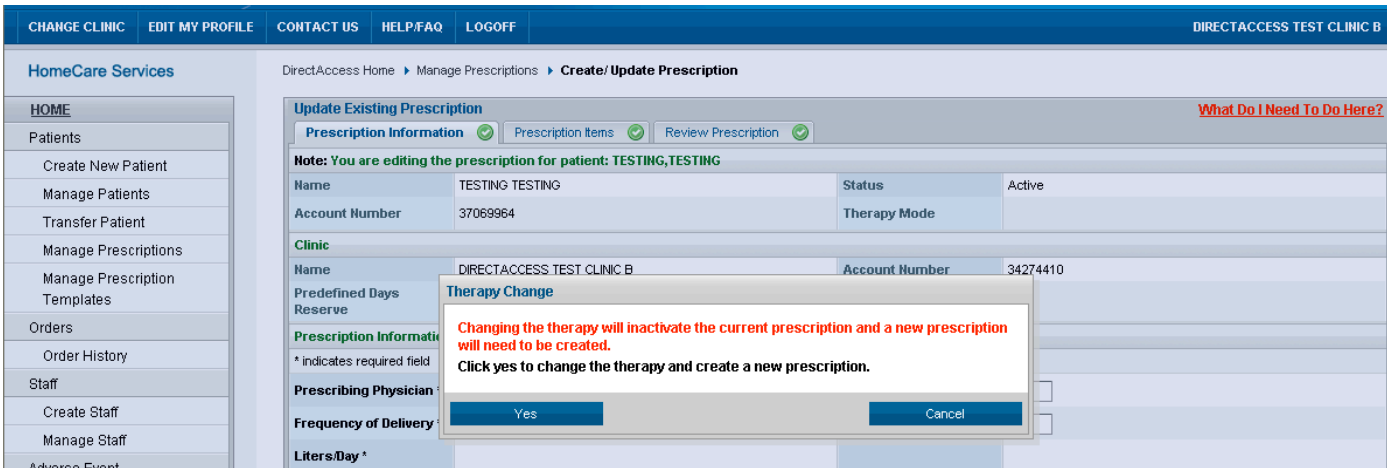
Example

2. Click the **View/Update** for the patient whose modality you wish to change; the system displays the **Prescription Information** tab of the **Create/Update Prescription** screen.



Example

3. Change the Therapy Mode using the **Therapy Mode** drop-down; the **Therapy Change** window appears with a message stating: "Changing the therapy will inactivate the current prescription and a new prescription will need to be created."



Example

4. Click Yes to create the new prescription. The system creates the new prescription and returns you to the **Prescription Information** tab of the **Create/Update Prescription** screen.

5. Change the following fields to reflect the patient's new therapy:

   - Liters/Day using the drop-down
   - Max Quantity

To figure out a 28 day Max Quantity supply with a five day reserve, use this grid:

5B MAX GRID
5-DAY Reserve Quantities per a 28-day cycle

Pack Factor	Number of bags used per day				
	1x day	2x day	3x day	4x day	5x day
2/CS	17	33	50	66	83
4/CS	9	17	25	33	42
5/CS	7	14	20	27	33
6/CS	6	11	17	22	28
8/CS	5	9	13	17	21
12/CS	3	6	9	11	14

From this point forward, the prescription is treated as a new prescription and follows the procedure as described in the Prescriptions User Guide; please consult that document for guidance on working prescriptions that appear in the Prescription To Do list.

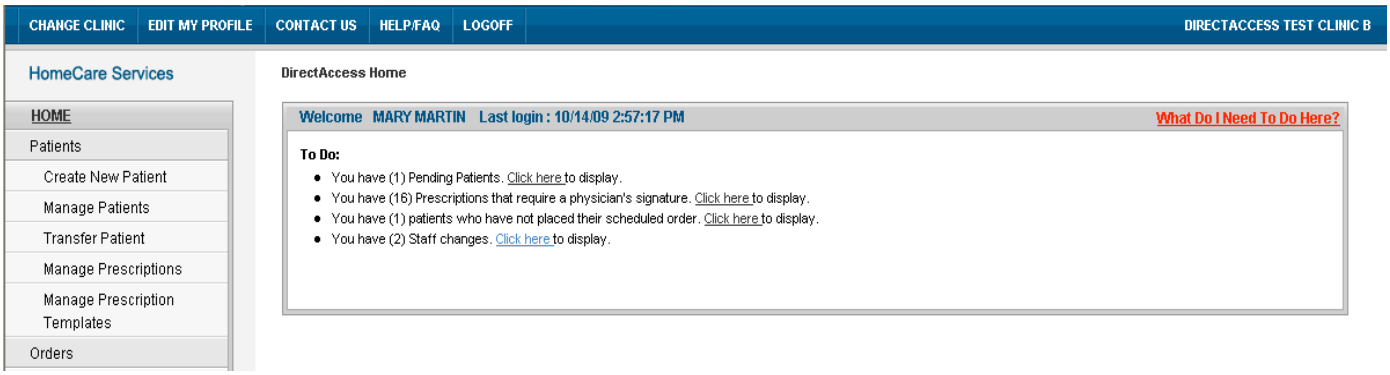
HomeCare Services

Managing Staff Changes

Managing Staff Changes (Site Administrators Only)

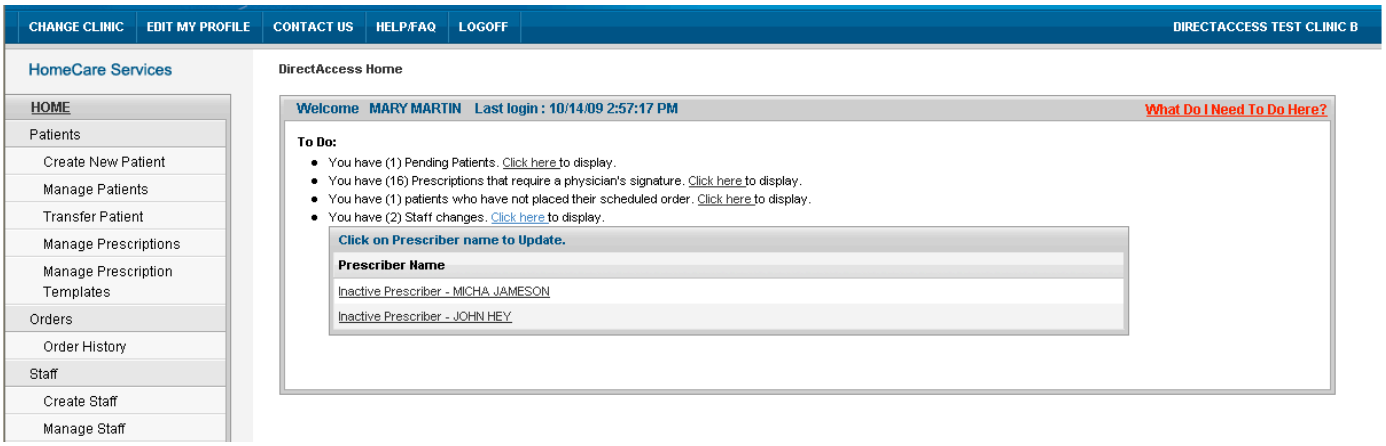
After logging on, the system displays the **DirectAccess** online tool Home Page.

The **To Do List** may contain a Staff changes note, which will list deactivated physicians whose patients need to be reassigned. The following steps will guide you through this process.


CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Orders
DirectAccess Home
Welcome MARY MARTIN Last login : 10/14/09 2:57:17 PM
What Do I Need To Do Here?
To Do:
You have (1) Pending Patients. Click here to display.
You have (16) Prescriptions that require a physician's signature. Click here to display.
You have (1) patients who have not placed their scheduled order. Click here to display.
You have (2) Staff changes. Click here to display.

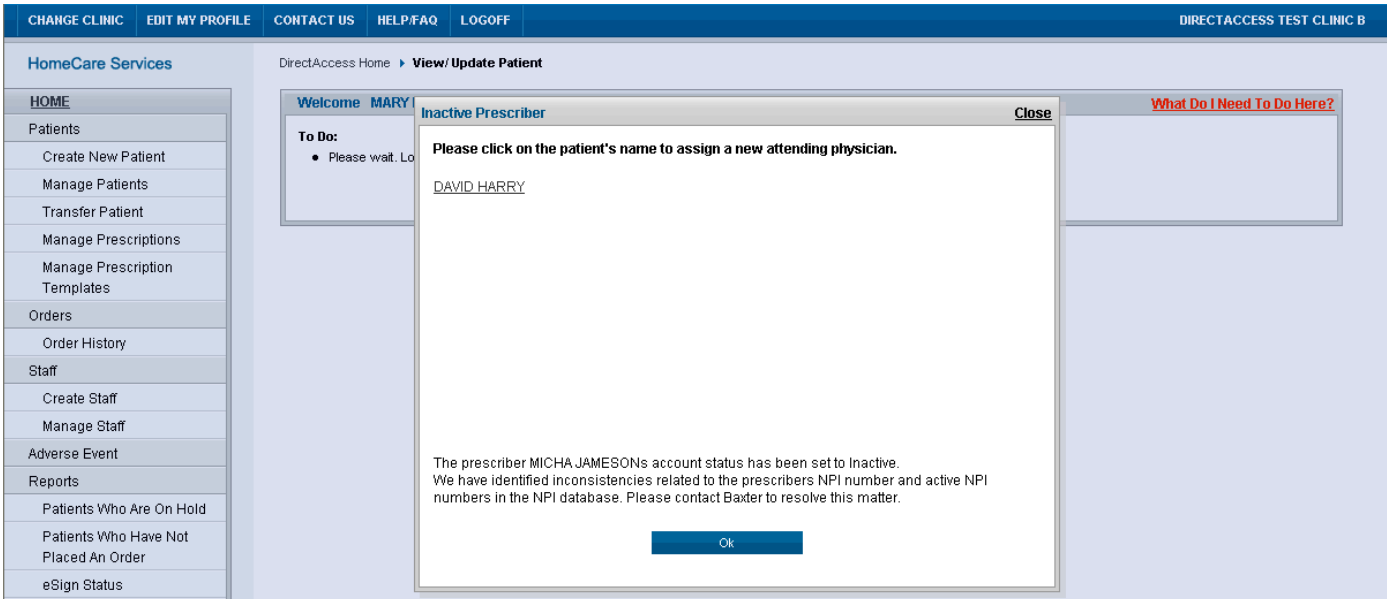
Example

1. To see a list of deactivated physicians whose patients need to be reassigned, click the **Click Here** link to display; the system displays the physicians (i.e., Inactive Prescribers) in a box below the link you just clicked.



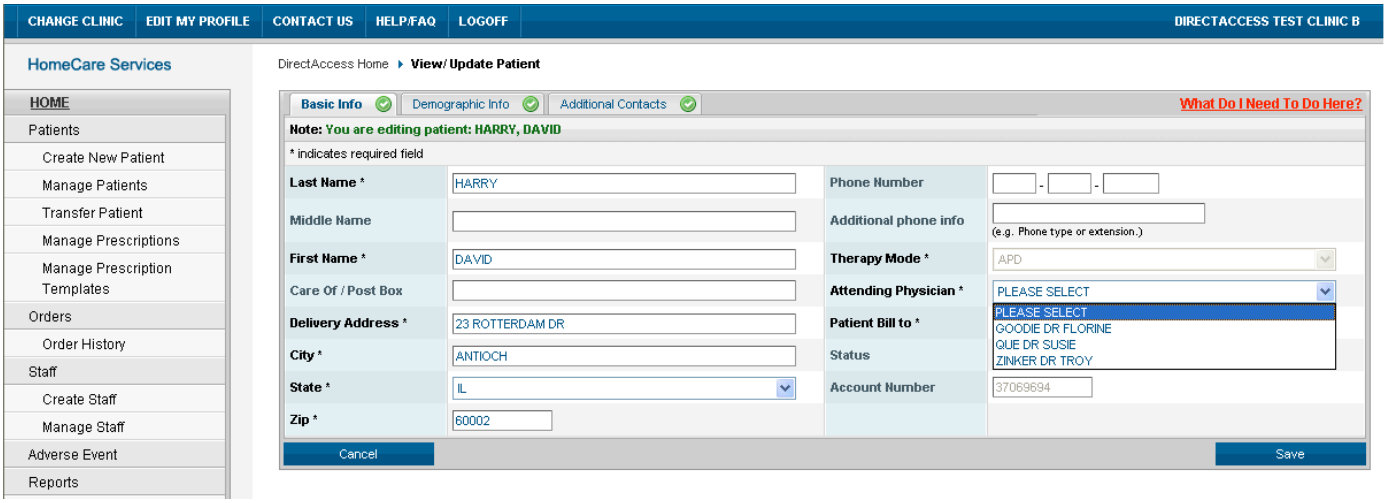
Example

2. Click on the physician name to update **Prescriber**; the system displays the list of patients requiring a new attending physician.



Example

3. Click on the patient's name to select a new attending physician. The system displays the **Basic Info** tab of the **View/Update Patient** screen with that patient's information. The note indicates the name of the patient you are editing.



Example

4. Select a new attending physician from the list in the drop-down in the **Attending Physician** field and click the **Save** button. The system updates the patient's information with the new attending physician and confirms that the information has been successfully saved.

5. Click on **HOME** from the left navigation bar to return to the To Do list.

6. Repeat the steps above until all patients are assigned a new attending physician.

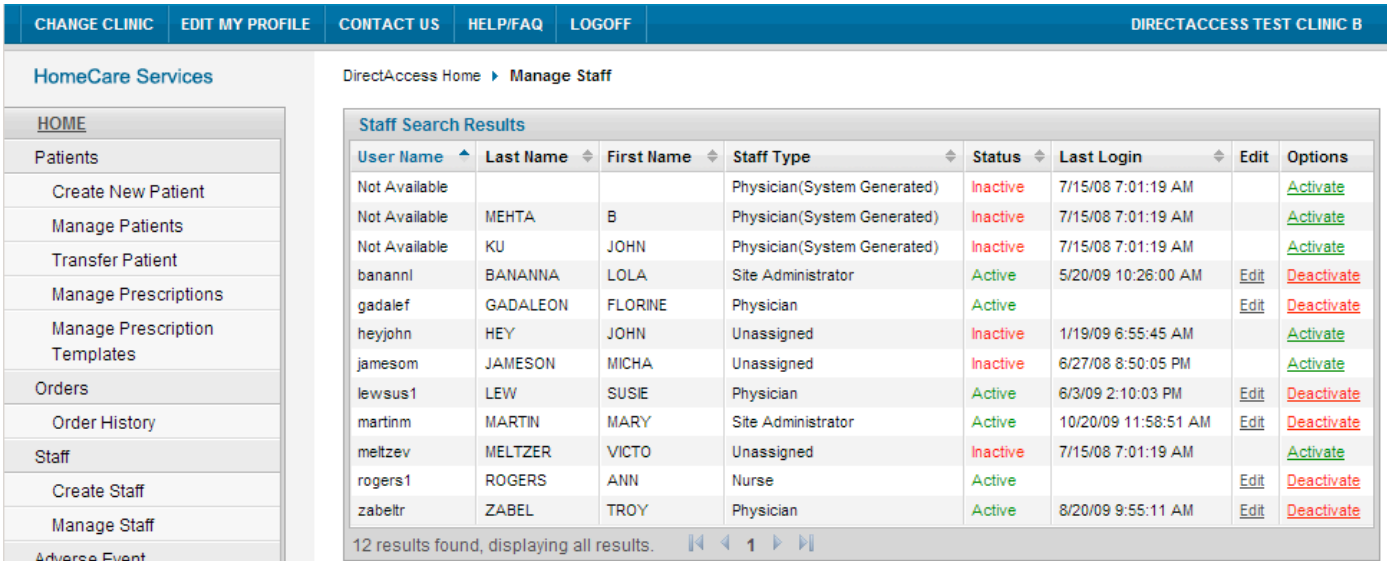
MANAGE STAFF

You may also make staff changes monthly and as needed using the **Manage Staff** and **Create Staff** links in the Navigation bar on the left. These changes include:

- Updating staff information, including staff type and staff details, assigning patients by staff member and assigning eSigning rights
- Activating and deactivating staff

You can also view a list of patients assigned to a particular staff member.

1. Click on **Manage Staff** in the left navigation bar; the system displays the Staff Search Results window.


CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Orders
Order History
Staff
Create Staff
Manage Staff
DirectAccess Home ▸ Manage Staff
Staff Search Results
User Name | Last Name | First Name | Staff Type | Status | Last Login | Edit | Options
Not Available | | | Physician(System Generated) | Inactive | 7/15/08 7:01:19 AM | | Activate
Not Available | MEHTA | B | Physician(System Generated) | Inactive | 7/15/08 7:01:19 AM | | Activate
Not Available | KU | JOHN | Physician(System Generated) | Inactive | 7/15/08 7:01:19 AM | | Activate
bananni | BANANNA | LOLA | Site Administrator | Active | 5/20/09 10:26:00 AM | Edit | Deactivate
gadalef | GADALEON | FLORINE | Physician | Active | | Edit | Deactivate
heyjohn | HEY | JOHN | Unassigned | Inactive | 1/19/09 6:55:45 AM | | Activate
jamesom | JAMESON | MICHA | Unassigned | Inactive | 6/27/08 8:50:05 PM | | Activate
lewsus1 | LEW | SUSIE | Physician | Active | 6/3/09 2:10:03 PM | Edit | Deactivate
martinm | MARTIN | MARY | Site Administrator | Active | 10/20/09 11:58:51 AM | Edit | Deactivate
meltzev | MELTZER | VICTO | Unassigned | Inactive | 7/15/08 7:01:19 AM | | Activate
rogers1 | ROGERS | ANN | Nurse | Active | | Edit | Deactivate
zabeltr | ZABEL | TROY | Physician | Active | 8/20/09 9:55:11 AM | Edit | Deactivate
12 results found, displaying all results.
1

Example

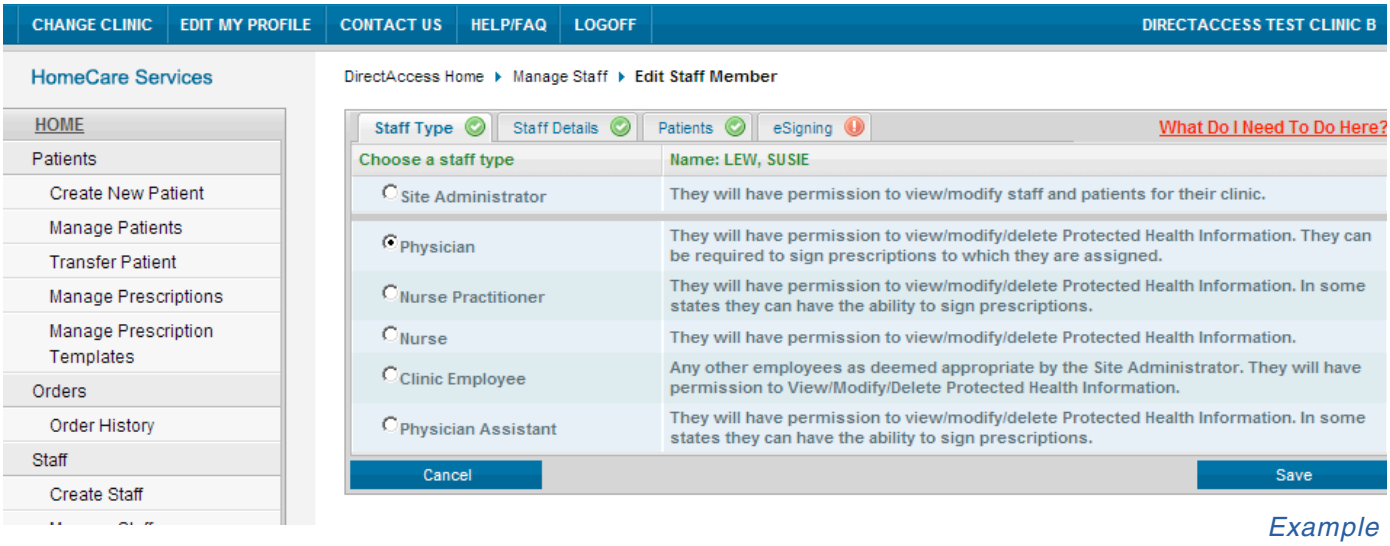
2. To make changes on a staff member's account, click the **Edit** link in the second column from the right. This will allow you to:

- Update staff type
- Update staff details
- Assign patients by staff member
- Assign eSigning rights

At the beginning of every month, the system will send you a reminder on the To Do List asking you to review your staff members' profiles and update if necessary.

MANAGE STAFF - UPDATE STAFF TYPE

The system displays the **Edit Staff Member** screen.


CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Orders
Order History
Staff
Create Staff
DirectAccess Home ▸ Manage Staff ▸ Edit Staff Member
Staff Type
Staff Details
Patients
eSigning
What Do I Need To Do Here?
Choose a staff type
Name: LEW, SUSIE
Site Administrator
They will have permission to view/modify staff and patients for their clinic.
Physician
They will have permission to view/modify/delete Protected Health Information. They can be required to sign prescriptions to which they are assigned.
Nurse Practitioner
They will have permission to view/modify/delete Protected Health Information. In some states they can have the ability to sign prescriptions.
Nurse
They will have permission to view/modify/delete Protected Health Information.
Clinic Employee
Any other employees as deemed appropriate by the Site Administrator. They will have permission to View/Modify/Delete Protected Health Information.
Physician Assistant
They will have permission to view/modify/delete Protected Health Information. In some states they can have the ability to sign prescriptions.
Cancel
Save

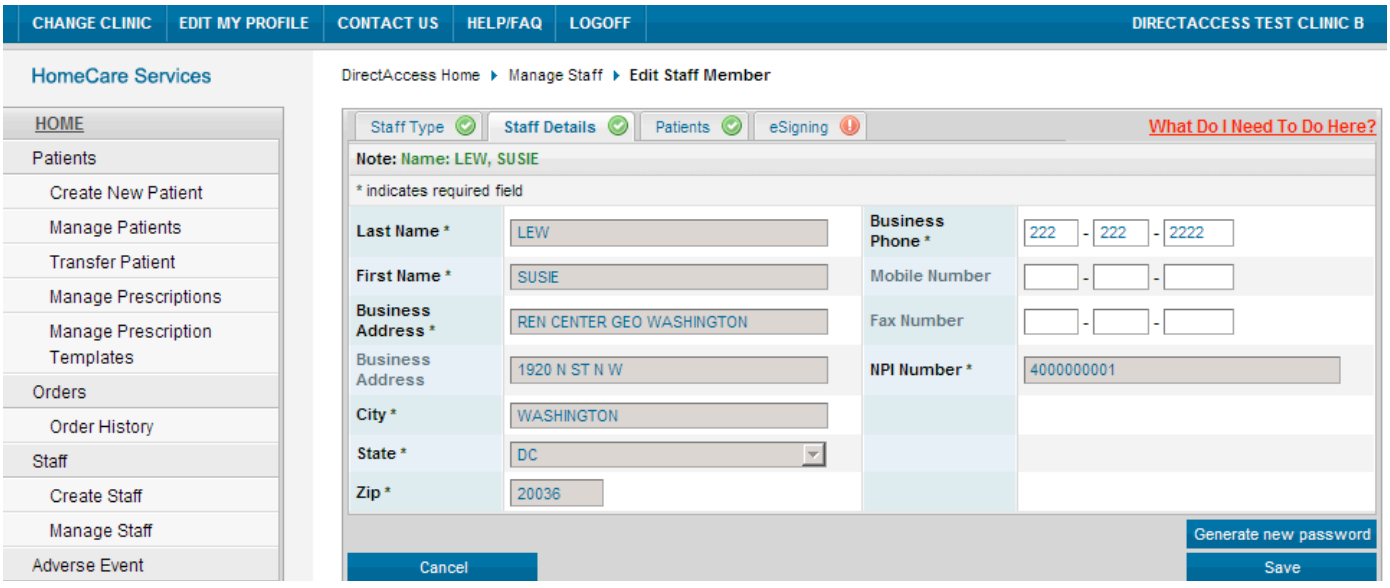
Example

1. If not displayed, click on the **Staff Type** tab. This allows you to change a staff member's role at the clinic.

2. Click the radio buttons to assign this staff member to another role and click **Save**; the system changes the role of the staff member.

MANAGE STAFF - UPDATE STAFF DETAILS

1. Click on the Staff Details tab; the system displays the Staff Details screen.



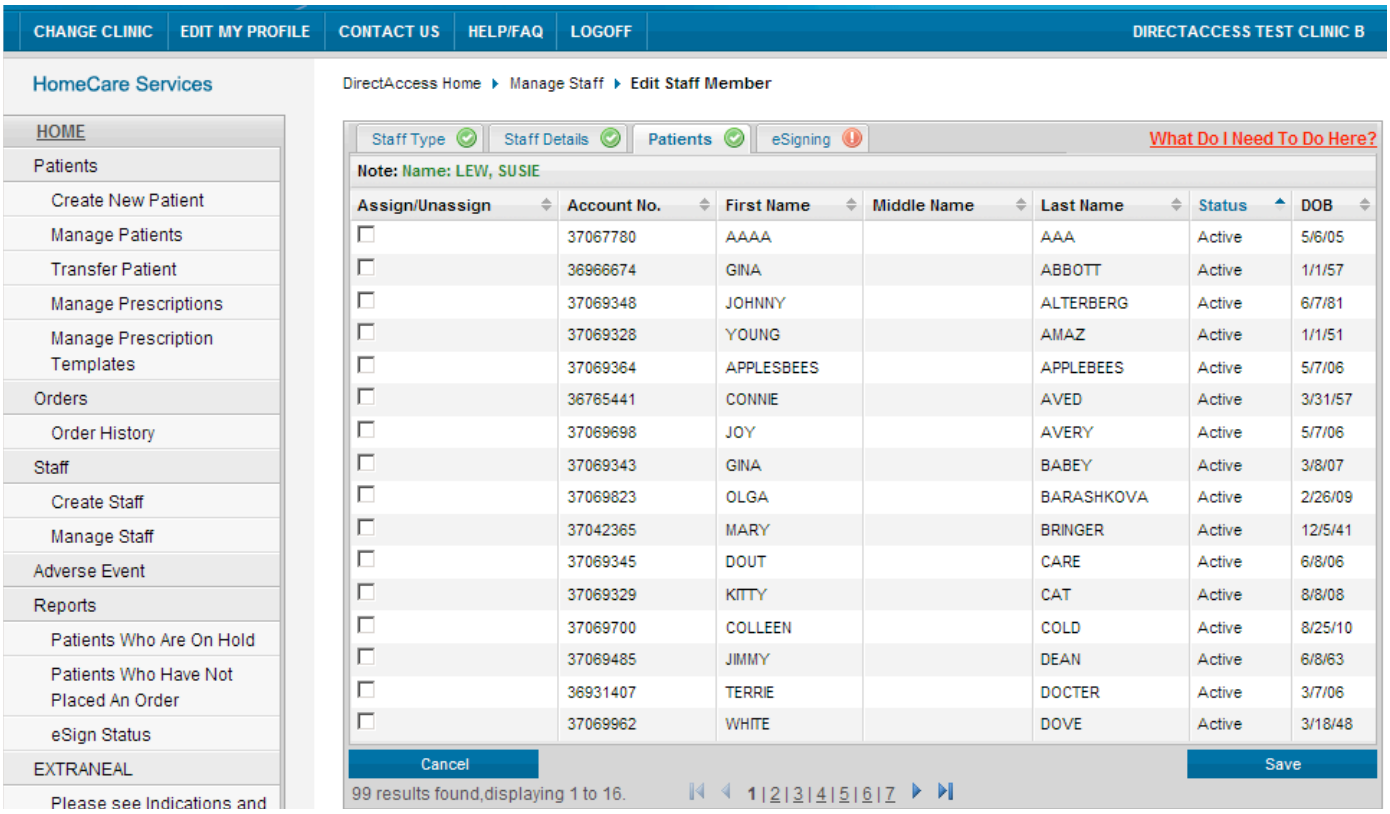
Example

2. Make any necessary changes and click **Save**; the system confirms the changes.

3. If a Staff Member forgets their password, verify the e-mail address and click on the **Generate New Password** button to send a new temporary password to the user's e-mail address; the system confirms that the password was sent.

MANAGE STAFF - ASSIGN PATIENTS BY STAFF MEMBER

1. To assign patients to a staff member, click on the **Patients** tab; the system displays the Patients screen which contains a list of all patients at the clinic.

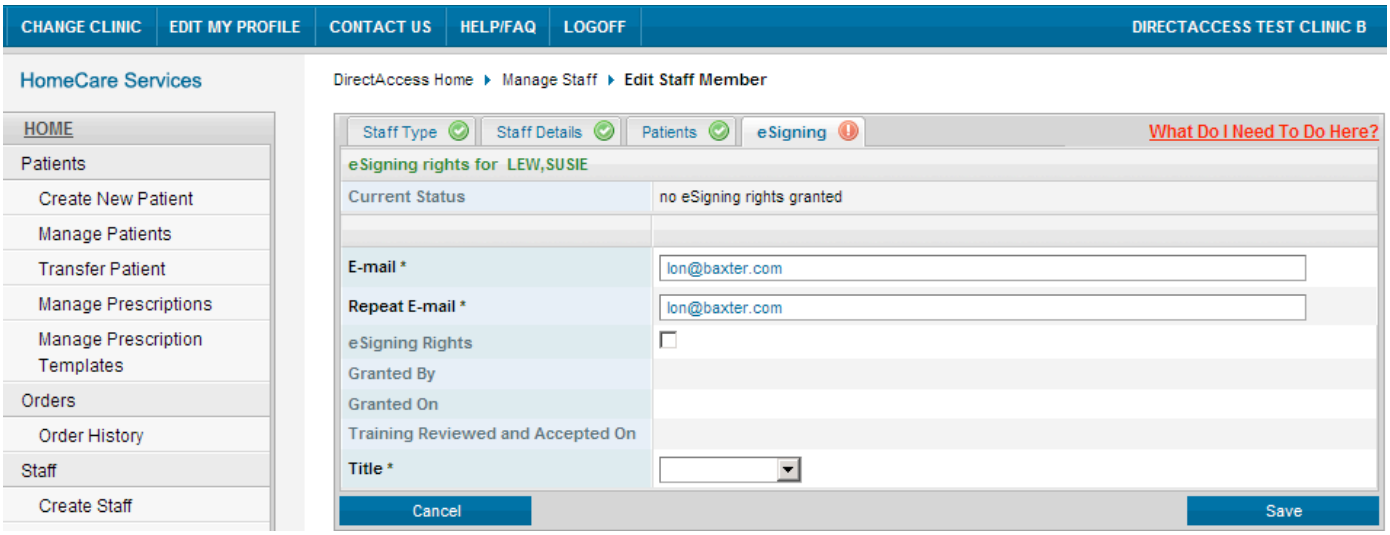


Example

2. Click the check box next to the patient's name to assign that patient to the staff member whose information you are updating. Click **Save** to save your information; the system confirms that the information has been successfully saved.

MANAGE STAFF - ASSIGN ESIGNING RIGHTS TO A STAFF MEMBER

1. To assign eSigning rights to a staff member, click on the **eSigning** tab; the system displays the **eSigning** screen.



Example

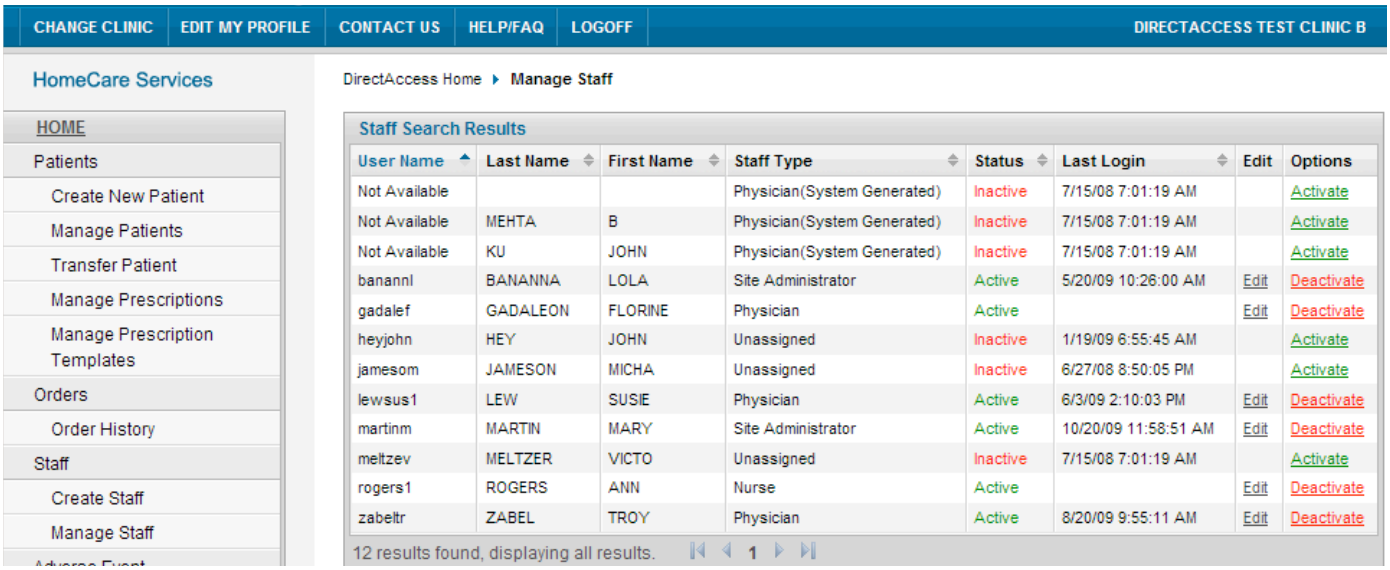
2. Click the **eSigning Rights** check box, make sure that the staff member's email has been entered in both fields, and select the staff member's title from the drop-down; these are required for eSigning.

3. Click **Save** to save your information; the system confirms that the information has been successfully saved.

A Site Administrator for each clinic is designated by Baxter and is responsible for providing user access rights depending on user role. Baxter makes no warranties or guarantees as to the identity of users utilizing **DirectAccess** online tool. You agree to use **DirectAccess** online tool for lawful and ethical purposes only.

MANAGE STAFF - ACTIVATE AND DEACTIVATE

1. Click on **Manage Staff** in the left navigation bar; the system displays the Staff Search Results window.


CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
DirectAccess Home ▸ Manage Staff
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Orders
Order History
Staff
Create Staff
Manage Staff
Staff Search Results
User Name | Last Name | First Name | Staff Type | Status | Last Login | Edit | Options
Not Available | | | Physician(System Generated) | Inactive | 7/15/08 7:01:19 AM | | Activate
Not Available | MEHTA | B | Physician(System Generated) | Inactive | 7/15/08 7:01:19 AM | | Activate
Not Available | KU | JOHN | Physician(System Generated) | Inactive | 7/15/08 7:01:19 AM | | Activate
bananni | BANANNA | LOLA | Site Administrator | Active | 5/20/09 10:26:00 AM | Edit | Deactivate
gadalef | GADALEON | FLORINE | Physician | Active | | Edit | Deactivate
heyjohn | HEY | JOHN | Unassigned | Inactive | 1/19/09 6:55:45 AM | | Activate
jamesom | JAMESON | MICHA | Unassigned | Inactive | 6/27/08 8:50:05 PM | | Activate
lewsus1 | LEW | SUSIE | Physician | Active | 6/3/09 2:10:03 PM | Edit | Deactivate
martinm | MARTIN | MARY | Site Administrator | Active | 10/20/09 11:58:51 AM | Edit | Deactivate
meltzev | MELTZER | VICTO | Unassigned | Inactive | 7/15/08 7:01:19 AM | | Activate
rogers1 | ROGERS | ANN | Nurse | Active | | Edit | Deactivate
zabeltr | ZABEL | TROY | Physician | Active | 8/20/09 9:55:11 AM | Edit | Deactivate
12 results found, displaying all results.
1

Example

2. To change the status, click on **Activate** or **Deactivate** in the Options column.

3. The system asks you to confirm the change; click **YES** to continue or **NO** to cancel.

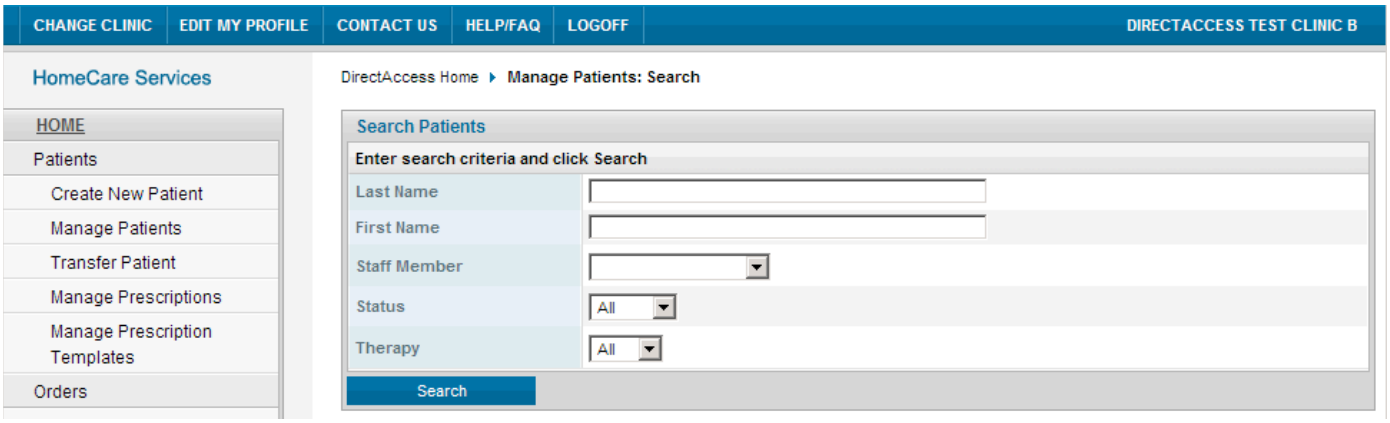
4. When you activate a staff member, you must also assign their role within the center. After you activate the staff member, the system displays the **Edit Staff Member** screen.

5. Click the radio buttons to assign the staff member to another role and click **Save**; the system assigns the new role of the activated staff member.

Note that the current status is displayed in red or green in the Status column.

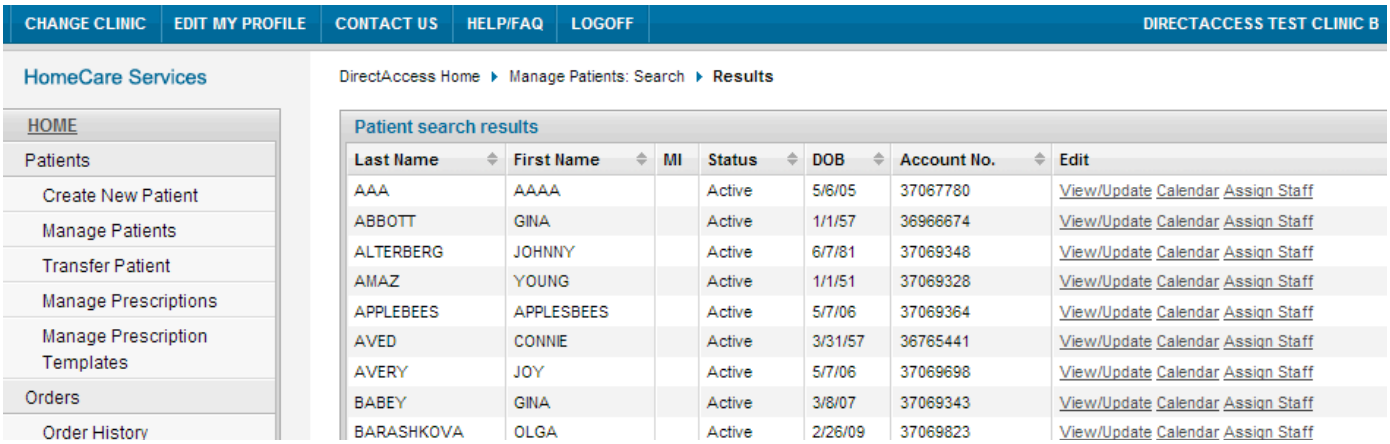
VIEW A LIST OF PATIENTS ASSIGNED TO A STAFF MEMBER

1. To view a list of patients assigned to a particular staff member, click on **Manage Patients** in the navigation bar on the left; the system displays the **Search Patients** box.



Example

2. To search by staff member name, click on **Staff Member** drop-down, select a **Staff Member** from the list provided and click **Search**. The system will display a list of patients assigned to that particular staff member.


CHANGE CLINIC
EDIT MY PROFILE
CONTACT US
HELP/FAQ
LOGOFF
DIRECTACCESS TEST CLINIC B
HomeCare Services
DirectAccess Home ▸ Manage Patients: Search ▸ Results
HOME
Patients
Create New Patient
Manage Patients
Transfer Patient
Manage Prescriptions
Manage Prescription Templates
Orders
Order History
Patient search results
Last Name | First Name | MI | Status | DOB | Account No. | Edit
AAA | AAAA | | Active | 5/6/05 | 37067780 | View/Update Calendar Assign Staff
ABBOTT | GINA | | Active | 1/1/57 | 36966674 | View/Update Calendar Assign Staff
ALTERBERG | JOHNNY | | Active | 6/7/81 | 37069348 | View/Update Calendar Assign Staff
AMAZ | YOUNG | | Active | 1/1/51 | 37069328 | View/Update Calendar Assign Staff
APPLEBEES | APPLESBEES | | Active | 5/7/06 | 37069364 | View/Update Calendar Assign Staff
AVED | CONNIE | | Active | 3/31/57 | 36765441 | View/Update Calendar Assign Staff
AVERY | JOY | | Active | 5/7/06 | 37069698 | View/Update Calendar Assign Staff
BABEY | GINA | | Active | 3/8/07 | 37069343 | View/Update Calendar Assign Staff
BARASHKOVA | OLGA | | Active | 2/26/09 | 37069823 | View/Update Calendar Assign Staff

Example

3. From this screen you can **View/Update** the patient, view the patient's Calendar, or assign the patient to another staff member by clicking the appropriate links.

HomeCare Services

Appendices

SIMPLE Report Guide

APPENDIX A1

This list reflects all of the terms displayed in the three sections of the SIMPLE Report (Patient Detail, Patient Summary and Product Summary). All reports do not contain all the data fields listed here. All of the terms defined here are used in one or more reports and the number of the data field is on the report samples attached.

1 550555A	Number identifies report (used internal Baxter).
2 Home Patient Customer Service	The #800 telephone number for placing product orders and making delivery inquires.
3 The Report Name	The name of the report
4 Date	For the most recent month's information displayed.
4a Range	The range of the dates for the included in this specific report.
5 Date and Time Page Number	Date and time the report is printed (generated). Page number (located in upper right hand corner) can be helpful if discussing report
6 Patient Detail	The name of the specific section of the SIMPLE Report: ex: Patient Detail, Product Detail or Product Summary
7 Facility #	Baxter assigned account number for Dialysis Facility
8 Facility Name	The name of the Dialysis Facility
9 Phone #	The telephone number for the Dialysis Facility
10 Territory	Baxter assigned sales territory
11 HCSR Name	The name of the primary HomeCare Service Representative (HCSR). Their telephone number is displayed @ #2 and their extension is #12.
12 Phone #	The HCSR telephone extension
Patient Information	
13 Patient Name	Patient name
14 Patient number	Patient number assigned by Baxter (different than the account number for the dialysis center)
15 Mode	Current therapy
16 Active Date	The date the patient started with the specified Dialysis Facility. Patients that are active with the Dialysis Facility will appear at the beginning of the report.
17 Inactive Date	Patients that are NOT active with the Dialysis Facility and have year-to-date values will be moved to the end of the report. The patient will remain on the report for the calendar year if activity has occurred.
	Prescription Information
18 SO/Rx Expiration Date	The expiration date of the Standing Order Prescription (SO/Rx)
19 5B Max	The prescribed monthly PD solution maximum denoted in the prescription as 5B Max.
20 Product Code	Baxter assigned product code number. LEASED HARDWARE is indicated by an (L) suffix on the product code ex: 5C4471L
21 Description	Baxter product name (description)
22 On SO Rx	The letter Y (yes) in the On SO/Rx column indicates a product currently on the patient's prescription. All products that are not currently active on the Rx but have had activity during the current year will appear on the report.
23 SO Rx Qty	Quantity prescribed.
ORDER INFORMATION	
Order numbers, invoice numbers and dates are provided for reference. Details for the current month along with summary information for the two prior months are listed.	
24 Order Qty	Quantity ordered on each specific order. Quantities are reported in the unit of measure indicated.
25 Extended Price	The sum of the order quantity multiplied by the current contract price per item. (on reports 55505A, 55505D and 55505E only)
26 Actual Ship Date	Date the product was actually shipped to the patient.
27 Order #	Order number for that specific product.
28 Invoice Date	Date the product is invoiced.
29 Invoice #	Invoice number for that specific product.
30 Summary Quantities	Shown for current active products: a. Current month b. One month prior c. Two months prior d. Year-to-date order quantity (YTD) e. Pack factor designator, cases (CA) or each (EA) f. Year-to-date dollars (on reports 55505A, 55505D and 55505E only) **Dollar amounts do not include tax. Totals reflect credits issued during the specified time frame. Specific questions regarding credits can be addressed to your Account Business Services Representative (ABS).
31 PD Solution Totals (5B)	a. 5B PD solutions total quantity for current month b. 5B PD solutions total quantity year-to-date
32 Patient Total Year-to-Date Dollars	Total patient quantity for year-to-date (YTD)
33 Patient Total Current Month Dollars	Total patient dollars for current month. (reports 55505A, 55505D and 55505E only)
34 Dialysis Facility Total Year-to-Date $	Total Dialysis Facility dollars for year-to-date (YTD) (on reports 55505A, 55505D and 55505E only)
35 Dialysis Facility Total Current Month $	Total Dialysis Facility dollars for current month. (on reports 55505D and E)

SIMPLE Report

APPENDIX A2

Baxter

1 55505A
Home Patient Customer Service
2 1-800-284-4060

3 SIMPLE Report
4 November, 2007
4a 11/01/07-11/31/07

5 Date…: 1/11/08
Time…:13:17:58
Page…: 1

6 Patient Detail

7 Facility #: 12345678
8 Facility Name: Kidney Dialysis Unit
9 Phone #: (123) 456-7890
10 Territory: 1111
11 HPSR Name. : Molly Representative
12 Phone #: EXT-0000

13 Patient Name.. : Annerp Mary
14 Patient Number: 87654321
15 Mode……... : APD Hosp/Center
16 Active Date…….. : 02/13/2007
17 Inactive Date…… :
18 SO/RX Expiration Date : 10/25/2008
19 5B Max: 99 CA

20 Product Code	Description 21	On SO RX	SO RX Qty	Order Qty 22	Extended Price 23	Actual Ship Date 24	Order # 26	Invoice Date 27	Invoice # 28	----Summary Quantities---- a Dec 2007	b Nov 2007	c Oct 2007	d YTD 2007 30	e	f YTD 2007 Dollars
5B9876	2.5% PD 2UB 2L/2L DNL	Y	99 CA	99 CA	999.99	99/99/2007	22222222	99/99/2007	11111111	99	99	99	999	CA	9,999.99
5B9896	4.25% PD2 UB 2L/2L DNL	Y	99 CA	99 CA	999.99	99/99/2007	22222222	99/99/2007	11111111	99	99	99	999	CA	9,999.99

31a Dec 5B Total……: 99 CA
YTD 5B Total……..: 999 CA

5C4466P	MINICAP DISCONNECT W/PVE	Y	9 CA	9 CA	999.99	99/99/2007	22222222	99/99/2007	11111111	9	99	99	999	CA	9,999.99
5K7792	GLV LATEX N/S LG EA=100	Y	9 EA	9 EA	999.99	99/99/2007	22222222	99/99/2007	11111111	999	999	999	9999	EA	9,999.99
5K8070	FACE MASK-YELLOW ELASTIC		0 EA							0	0	999	9999	EA	9,999.99

33 Patient Total Current Month Dollars: 9,999.99
32 Patient Total YTD Dollars 99,999.99

Baxter

1 55505A
Home Patient Customer Service
2 1-800-284-4060

3 SIMPLE Report
4 November, 2007
4a 11/01/07-11/31/07

5 Date…: 1/11/08
Time :13:17:58
Page…: 1

6 Patient Summary

7 Facility #: 12345678
8 Facility Name: Kidney Dialysis Unit
9 Phone #: (123) 456-7890
10 Territory: 1111

13 Patient 14 Name/Nbr	16 Active Date	17 Inactive Date	Dollars Invoiced 33 Dec 2007	Nov 2007	Oct 2007	Q1 2007	Q2 2007	Q3 2007	Q4 2007	32 YTD 2007
ANNERP MARY			9,999.99	9,999.99	9,999.99	0	0	0	99,999	99,999
87654321	02/13/2007									
SMITH BRIAN			9,999.99	9,999.99	9,999.99	0	0	0	99,999	99,999
55544433	05/18/2007									
ASCOTT STEVE			.00	.00	9,999.99	0	0	0	9,999	9,999
22233344	02/05/2007	11/03/2007								
35 Facility Total:			99,999.99	99,999.99	99,999.99	0	0	0	999,999	34 999,999

---

1 55505A
Home Patient Customer Service
2 1-800-284-4060

3 SIMPLE Report
4 November, 2007
4a 11/01/07-11/31/07

5 Date…: 1/11/08
Time…:13:17:58
Page…: 1

6 Product Summary

7 Facility #: 12345678
8 Facility Name: Kidney Dialysis Unit
9 Phone #: (123)456-7890
10 Territory: 1111

20 Product Code	Description 21	Pack Factor	December 30a Quantity	33 Dollars Invoiced	YTD 30d Quantity	30f Dollars Invoiced
5B9876	2.5% PD2 UB 2L/2L DNL	6/CA	99 CA	999.99	999 CA	9,999
5B9896	4.25% PD2 UB 2L/2L DNL	6/CA	99 CA	999.99	999 CA	9,999
5C4466P	MINICAP DISCONNECT W/PVE	60/CA	99 CA	999.99	999 CA	9,999
5K7792	GLV LATEX N/S LG EA=100	PK	99 EA	999.99	999 EA	9,999
5K8070	FACE MASK-YELLOW ELASTIC	<50/BX	999 EA	999.99	999 EA	9,999

35 Facility Total: 9,999.99
34 999,999

RN/Patient Training Checklist

APPENDIX B

Patient Inventory Management

- Emphasize the importance of good inventory management with the patient. Establish that the patient is expected to work with Baxter and the unit to maintain appropriate supply levels in their home

- Review inventory management procedure with patient:
  - On or near the date of order placement, the patient must take an ACCURATE and complete inventory of all UNOPENED boxes (including reserve boxes) and document the count on the inventory form
  - During order placement, the patient must provide the information from the completed inventory to their HCSR
  - During order placement, the patient also must provide their Baxter HCSR with their daily solution usage and any variations, which can also be captured on the inventory form

- Review proper product stocking levels with patient:
  - Upon delivery, the patient should have enough product to get them to their next scheduled delivery date, plus a reserve stock to compensate for usage changes and/or other emergencies
  - If a patient thinks they may not have enough product to get them to their next delivery date, they should call their HCSR immediately
  - Instruct the patient to call their HCSR whenever their prescription changes or when their solution strength usage changes significantly, to help avoid potential stockout situations

- Communicate the importance of adhering to the order and delivery schedule that Baxter supplies to each home patient

- Emphasize the importance of keeping supplies as close together in the home as possible. The drivers need to see all the supplies to ensure optimal inventory levels are maintained

Success of this program requires commitment from Baxter, the dialysis unit staff and the patient!

Home Patient Inventory Form

APPENDIX C

Baxter

Renal Division
The Original HOME PATIENT INVENTORY FORM

Date Supplies Are Counted: _____ **Next Count Date:** _____

Please count and enter in the appropriate space below the number of full cases on hand and usage. Be sure to include your reserve stock in your count and to notify Baxter of any usage changes.

Dialysis Solution	1L		1.5L		2L		2.5L		3L		5L		6L	
	On Hand	Usage	On Hand	Usage	On Hand	Usage	On Hand	Usage	On Hand	Usage	On Hand	Usage	On Hand	Usage
Yellow 1.5%														
Green 2.5%														
Red 4.25%														
Purple 7.5%														

		Other Supplies	
Caps			
Cassettes/Cycler Tubing			
Drain Line			
Drain Bag			
Patient Extensions			
Y-Sets			

Supplies should be stored in the following manner:

- At room temperature
- Avoid excessive heat or freezing
- Avoid insect/rodent infestation
- Avoid liquid contamination
- Store away from chemicals

Notes

_____

_____

_____

_____

_____

Name: _____

To place your order, call

1-800-284-4060

Ambuflex Luer Lock (SYS II) Bag Codes

PD Solutions

LITER SIZE	DIANEAL PD-2	DIANEAL LOW CAL	EXTRANEAL (icodextrin)
1 L 12/CS	L5B5163		
	L5B5173		
	L5B5183		
2 L 6/CS	L5B5166	L5B4825	L5B4974
	L5B5177	L5B9727	
	L5B5187	L5B9747	
2.5 L			L5B4976
3 L 4/CS	L5B5169	L5B9901	
	L5B5179	L5B9902	
	L5B5189	L5B9903	
5 L 2/CS	L5B5193	L5B4826	
	L5B5194	L5B5202	
	L5B5195	L5B5203	
6 L 2/CS	L5B9710	L5B9770	
	L5B9711	L5B9771	
	L5B9712	L5B9772	

KEY
1.5%
2.5%
4.25%
EXTRANEAL

Refer to Appendix E for Baxter's PD Solution package inserts.

Luer Disposable Set Codes

DESCRIPTION	LUER CODE NUMBER
3-Prong Integrated Set	L5C4531
4-Prong APD Set	R5C4479C
Low Recirculation APD Set	N5C8305C
5-Prong Manifold Set, 200 mm	L5C4446
UltraSet Disposable Disconnect Y Set	L5C4366

Baxter

EXTRANEAL
(icodextrin) Peritoneal Dialysis Solution

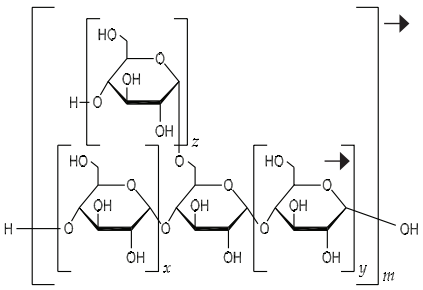
Dangerous Drug-Device Interaction
Only use glucose-specific monitors and test strips to measure blood glucose levels in patients using EXTRANEAL (icodextrin) Peritoneal Dialysis Solution. Blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO)-based methods must not be used. In addition, some blood glucose monitoring systems using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods must not be used. Use of GDH-PQQ, GDO, and GDH-FAD-based glucose monitors and test strips has resulted in falsely elevated glucose readings (due to the presence of maltose, see **PRECAUTIONS/Drug/Laboratory Test Interactions).** Falsely elevated glucose readings have led patients or health care providers to withhold treatment of hypoglycemia or to administer insulin inappropriately. Both of these situations have resulted in unrecognized hypoglycemia, which has led to loss of consciousness, coma, permanent neurological damage, and death. Plasma levels of EXTRANEAL (icodextrin) and its metabolites return to baseline within approximately 14 days following cessation of EXTRANEAL (icodextrin) administration. Therefore falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL (icodextrin) therapy when GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors and test strips are used.

Because GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of peritoneal dialysis patients using EXTRANEAL (icodextrin) carefully review the product information of the blood glucose testing system, including that of test strips, to determine if the system is appropriate for use with EXTRANEAL (icodextrin).

To avoid improper insulin administration, educate patients to alert health care providers of this interaction whenever they are admitted to the hospital.

The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose readings. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP or visit www.glucosesafety.com.

DESCRIPTION
EXTRANEAL (icodextrin) Peritoneal Dialysis Solution is a peritoneal dialysis solution containing the colloid osmotic agent icodextrin. Icodextrin is a starch-derived, water-soluble glucose polymer linked by alpha (1-4) and less than 10% alpha (1-6) glucosidic bonds with a weight-average molecular weight between 13,000 and 19,000 Daltons and a number average molecular weight between 5,000 and 6,500 Daltons. The representative structural formula of icodextrin is:



Each 100 mL of EXTRANEAL contains:

Icodextrin	7.5 g
Sodium Chloride, USP	535 mg
Sodium Lactate	448 mg
Calcium Chloride, USP	25.7 mg
Magnesium Chloride, USP	5.08 mg
Electrolyte content per liter:	
Sodium	132 mEq/L
Calcium	3.5 mEq/L
Magnesium	0.5 mEq/L
Chloride	96 mEq/L
Lactate	40 mEq/L

Water for Injection, USP qs
HCl/NaOH may have been used to adjust pH.
EXTRANEAL contains no bacteriostatic or antimicrobial agents.
Calculated osmolarity: 282–286 mOsm/L; pH=5.0-6.0

EXTRANEAL is available for intraperitoneal administration only as a sterile, nonpyrogenic, clear solution in AMBU-FLEX II, AMBU-FLEX III and ULTRABAG containers. The container systems are composed of polyvinyl chloride.

Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY
Mechanism of Action
EXTRANEAL is an isosmotic peritoneal dialysis solution containing glucose polymers (icodextrin) as the primary osmotic agent. Icodextrin functions as a colloid osmotic agent to achieve ultrafiltration during long peritoneal dialysis dwells. Icodextrin acts in the peritoneal cavity by exerting osmotic pressure across small intercellular pores resulting in transcapillary ultrafiltration throughout the dwell. Like other peritoneal dialysis solutions, EXTRANEAL also contains electrolytes to help normalize electrolyte balance and lactate to help normalize acid-base status.

Pharmacokinetics of Icodextrin
Absorption
Absorption of icodextrin from the peritoneal cavity follows zero-order kinetics consistent with convective transport via peritoneal lymphatic pathways. In a single-dose pharmacokinetic study using EXTRANEAL (icodextrin), a median of 40% (60 g) of the instilled icodextrin was absorbed from the peritoneal solution during a 12-hour dwell. Plasma levels of icodextrin rose during the dwell and declined after the dwell was drained. Peak plasma levels of icodextrin plus its metabolites (median C_{peak} 2.2g/L) were observed at the end of the long dwell exchange (median T_{max} = 13 hours).

At steady-state, the mean plasma level of icodextrin plus its metabolites was about 5 g/L. In multidose studies, steady-state levels of icodextrin were achieved within one week. Plasma levels of icodextrin and metabolites return to baseline values within approximately two weeks following cessation of icodextrin administration.

Metabolism
Icodextrin is metabolized by alpha-amylase into oligosaccharides with a lower degree of polymerization (DP), including maltose (DP2), maltotriose (DP3), maltotetraose (DP4), and higher molecular weight species. In a single dose study, DP2, DP3 and DP4 showed a progressive rise in plasma concentrations with a profile similar to that for total icodextrin, with peak values reached by the end of the dwell and declining thereafter. Only very small increases in blood levels of larger polymers were observed. Steady-state plasma levels of icodextrin metabolites were achieved within one week and stable plasma levels were observed during long-term administration.

Some degree of metabolism of icodextrin occurs intraperitoneally with a progressive rise in the concentration of the smaller polymers in the dialysate during the 12-hour dwell.

Elimination
Icodextrin undergoes renal elimination in direct proportion to the level of residual renal function. Diffusion of the smaller icodextrin metabolites from plasma into the peritoneal cavity is also possible after systemic absorption and metabolism of icodextrin.

Special Populations
Geriatrics
The influence of age on the pharmacokinetics of icodextrin and its metabolites was not assessed.
Gender and Race
The influence of gender and race on the pharmacokinetics of icodextrin and its metabolites was not assessed.

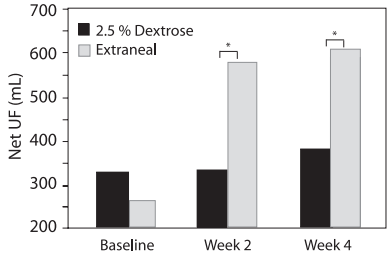
Clinical Studies
EXTRANEAL has demonstrated efficacy as a peritoneal dialysis solution in clinical trials of approximately 480 patients studied with end-stage renal disease (ESRD).

Ultrafiltration, Urea and Creatinine Clearance
In the active-controlled trials of one to six months in duration, described below, EXTRANEAL used once-daily for the long dwell in either continuous ambulatory peritoneal dialysis (CAPD) or automated peritoneal dialysis (APD) therapy resulted in higher net ultrafiltration than 1.5% and 2.5% dextrose solutions, and higher creatinine and urea nitrogen clearances than 2.5% dextrose. Net ultrafiltration was similar to 4.25% dextrose across all patients in these studies. Effects were generally similar in CAPD and APD.

In an additional randomized, multicenter, active-controlled two-week study in high average/high transporter APD patients, EXTRANEAL used once daily for the long dwell produced higher net ultrafiltration compared to 4.25% dextrose. Mean creatinine and urea nitrogen clearances were also greater with EXTRANEAL and ultrafiltration efficiency was improved.

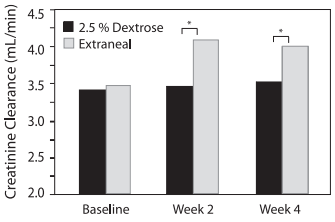
In 175 CAPD patients randomized to EXTRANEAL (N=90) or 2.5% dextrose solution (N=85) for the 8-15 hour overnight dwell for one month, mean net ultrafiltration for the overnight dwell was significantly greater in the EXTRANEAL group at weeks 2 and 4 (Figure 1). Mean creatinine and urea nitrogen clearances were also greater with EXTRANEAL (Figure 2).

Figure 1 - Mean Net Ultrafiltration for the Overnight Dwell

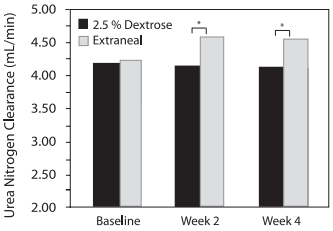


*p<0.001 EXTRANEAL vs. 2.5% dextrose (adjusted for baseline)

Figure 2 - Mean Creatinine and Urea Nitrogen Clearance for the Overnight Dwell



*p<0.001 EXTRANEAL vs. 2.5% dextrose (adjusted for baseline)



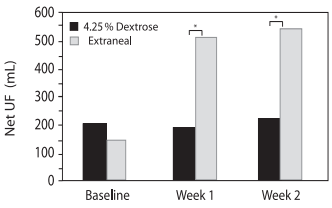
*p<0.001 EXTRANEAL vs. 2.5% dextrose (adjusted for baseline)

In another study of 39 APD patients randomized to EXTRANEAL or 2.5% dextrose solution for the long, daytime dwell (10-17 hours) for three months, the net ultrafiltration reported during the treatment period was (mean ± SD) 278 ± 192 mL for the EXTRANEAL group and –138 ± 352 mL for the dextrose group ($p<0.001$). Mean creatinine and urea nitrogen clearances were significantly greater for EXTRANEAL than 2.5% dextrose at weeks 6 and 12 ($p<0.001$).

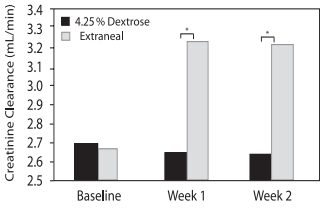
In a six-month study in CAPD patients comparing EXTRANEAL (n=28) with 4.25% dextrose (n=31), net ultrafiltration achieved during an 8-hour dwell averaged 510 mL for EXTRANEAL and 556 mL for 4.25% dextrose. For 12-hour dwells, net ultrafiltration averaged 575 mL for EXTRANEAL (n=29) and 476 mL for 4.25% dextrose (n=31). There was no significant difference between the two groups with respect to ultrafiltration.

In a two week study in high average/high transporter APD patients (4-hour D/P creatinine ratio >0.70 and a 4-hour D/D_0 ratio <0.34, as defined by the peritoneal equilibration test (PET)), comparing EXTRANEAL (n=47) to 4.25% dextrose (n=45), after adjusting for baseline, the mean net ultrafiltration achieved during a 14 ± 2 hour dwell was significantly greater in the EXTRANEAL group than the 4.25% dextrose group at weeks 1 and 2 ($p<0.001$, see Figure 3). Consistent with increases in net ultrafiltration, there were also significantly greater creatinine and urea nitrogen clearances and ultrafiltration efficiency in the EXTRANEAL group ($p<0.001$, see Figure 3).

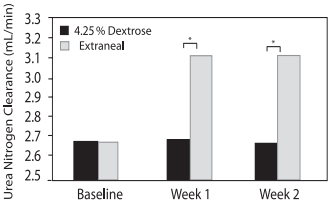
Figure 3 – Mean Net Ultrafiltration, Creatinine and Urea Nitrogen Clearances and Ultrafiltration Efficiency for the Long Dwell in High Average/High Transporter Patients



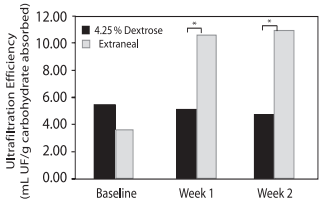
*p<0.001 EXTRANEAL vs. 4.25% dextrose (adjusted for baseline)



*p<0.001 EXTRANEAL vs. 4.25% dextrose (adjusted for baseline)



*p<0.001 EXTRANEAL vs. 4.25% dextrose (adjusted for baseline)



*p<0.001 EXTRANEAL vs. 4.25% dextrose (adjusted for baseline)

Peritoneal Membrane Transport Characteristics:
After one year of treatment with EXTRANEAL during the long dwell exchange, there were no differences in membrane transport characteristics for urea and creatinine. The mass transfer area coefficients (MTAC) for urea, creatinine, and glucose at one year were not different in patients receiving treatment with EXTRANEAL or 2.5% dextrose solution for the long dwell.

INDICATIONS AND USAGE

EXTRANEAL is indicated for a single daily exchange for the long (8- to 16- hour) dwell during continuous ambulatory peritoneal dialysis (CAPD) or automated peritoneal dialysis (APD) for the management of end-stage renal disease. EXTRANEAL is also indicated to improve (compared to 4.25% dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in patients with high average or greater transport characteristics, as defined using the peritoneal equilibration test (PET). (See **CLINICAL PHARMACOLOGY**, **Clinical Studies**)

CONTRAINDICATIONS

EXTRANEAL (icodextrin) is contraindicated in patients with a known allergy to cornstarch or icodextrin, in patients with maltose or isomaltose intolerance, in patients with glycogen storage disease, and in patients with pre-existing severe lactic acidosis.

WARNINGS

Dangerous Drug-Device Interaction (See **BOXED WARNING**)

Only use glucose-specific monitors and test strips to measure blood glucose levels in patients using EXTRANEAL (icodextrin) Peritoneal Dialysis Solution. Blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO)-based methods must not be used. In addition, some blood glucose monitoring systems using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods must not be used. Use of GDH-PQQ, GDO, and GDH-FAD-based glucose monitors and test strips has resulted in falsely elevated glucose readings (due to the presence of maltose, see **PRECAUTIONS/Drug/Laboratory Test Interactions**). Falsely elevated glucose readings have led patients or health care providers to withhold treatment of hypoglycemia or to administer insulin inappropriately. Both of these situations have resulted in unrecognized hypoglycemia, which has led to loss of consciousness, coma, permanent neurological damage, and death. Plasma levels of EXTRANEAL (icodextrin) and its metabolites return to baseline within approximately 14 days following cessation of EXTRANEAL (icodextrin) administration. Therefore falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL (icodextrin) therapy when GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors and test strips are used.

Because GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of peritoneal dialysis patients using EXTRANEAL (icodextrin) carefully review the product information of the blood glucose testing system, including that of test strips, to determine if the system is appropriate for use with EXTRANEAL (icodextrin).

To avoid improper insulin administration, educate patients to alert health care providers of this interaction whenever they are admitted to the hospital.

The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose readings. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP or visit www.glucosesafety.com.

EXTRANEAL is intended for intraperitoneal administration only. Not for intravenous injection.

Encapsulating peritoneal sclerosis (EPS) is a known, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including EXTRANEAL(icodextrin). Infrequent but fatal outcomes have been reported.

If peritonitis occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to the identification of the involved organism(s), broad-spectrum antibiotics may be indicated.

Rarely, serious hypersensitivity reactions to EXTRANEAL have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and leukocytoclastic vasculitis. If a serious reaction is suspected, discontinue EXTRANEAL and institute appropriate treatment as clinically indicated.

Patients with severe lactic acidosis should not be treated with lactate-based peritoneal dialysis solutions (See **CONTRAINDICATIONS**). It is recommended that patients with conditions known to increase the risk of lactic acidosis [e.g., acute renal failure, inborn errors of metabolism, treatment with drugs such as metformin and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)] must be monitored for occurrence of lactic acidosis before the start of treatment and during treatment with lactate-based peritoneal dialysis solutions.

When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysis treatment and therapy directed at other existing illnesses. Serum potassium levels should be monitored carefully in patients treated with cardiac glycosides. For example, rapid potassium removal may create arrhythmias in cardiac patients using digitalis or similar drugs; digitalis toxicity may be masked by hyperkalemia, hypermagnesemia, or hypocalcemia. Correction of electrolytes by dialysis may precipitate signs and symptoms of digitalis excess. Conversely, toxicity may occur at suboptimal dosages of digitalis if potassium is low or calcium high.

PRECAUTIONS

General

Peritoneal Dialysis-Related

The following conditions may predispose to adverse reactions to peritoneal dialysis procedures: abdominal conditions, including uncorrectable mechanical defects that prevent effective PD or increase the risk of infection, disruption of the peritoneal membrane and diaphragm by surgery, congenital anomalies or trauma prior to complete healing, abdominal tumors, abdominal wall infections, hernias, fecal fistula, colostomies or ileostomies, frequent episodes of diverticulitis, inflammatory or ischemic bowel disease, large polycystic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity, such as documented loss of peritoneal function or extensive adhesions that compromise peritoneal function. Conditions that preclude normal nutrition, impaired respiratory function, recent aortic graft placement, and potassium deficiency may also predispose to complications of peritoneal dialysis.

Aseptic technique should be employed throughout the peritoneal dialysis procedure to reduce the possibility of infection.

Following use, the drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis.

Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Treatment of overinfusion is to drain the peritoneal dialysis solution from the peritoneal cavity.

Need for Trained Physician

Treatment should be initiated and monitored under the supervision of a physician knowledgeable in the management of patients with renal failure.

A patient's volume status should be carefully monitored to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion and hypovolemic shock. An accurate fluid balance record must be kept and the patient's body weight monitored.

Significant losses of protein, amino acids, water-soluble vitamins and other medicines may occur during peritoneal dialysis. The patient's nutritional status should be monitored and replacement therapy should be provided as necessary.

In patients with hypercalcemia, particularly in those on low-calcium peritoneal dialysis solutions, consideration should be given to the fact that EXTRANEAL is not provided in a low-calcium electrolyte solution.

Solutions that are cloudy, contain particulate matter, or show evidence of leakage should not be used.

Insulin-dependent diabetes mellitus

Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment with EXTRANEAL. Appropriate monitoring of blood glucose should be performed and insulin dosage adjusted if needed (See **WARNINGS; PRECAUTIONS, Drug/Laboratory Test Interactions**).

Information for Patients.

Patients should be instructed not to use solutions if they are cloudy, discolored, contain visible particulate matter, or if they show evidence of leaking containers.

Aseptic technique should be employed throughout the procedure.

To reduce possible discomfort during administration, patients should be instructed that solutions may be warmed to 37°C (98°F) prior to use. Only dry heat should be used. It is best to warm solutions within the overwrap using a heating pad. To avoid contamination, solutions should not be immersed in water for warming. Do not use a microwave oven to warm EXTRANEAL. Heating the solution above 40°C (104°F) may be detrimental to the solution. (See **DOSAGE AND ADMINISTRATION**, Directions for Use).

Because the use of EXTRANEAL interferes with glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ), glucose-dye-oxidoreductase (GDO), and some GDH-FAD-based blood glucose measurements, patients must be instructed to use only glucose-specific glucose monitors and test strips. (See **WARNINGS; PRECAUTIONS, Drug/Laboratory Test Interactions**).

A Patient Medication Guide is provided in each carton of EXTRANEAL.

Laboratory Tests

Serum Electrolytes

Decreases in serum sodium and chloride have been observed in patients using EXTRANEAL. The mean change in serum sodium from baseline to the last study visit was –2.8 mmol/L for patients on EXTRANEAL and –0.3 mmol/L for patients on control solution. Four EXTRANEAL patients and two control patients developed serum sodium < 125 mmol/L. The mean change in serum chloride from baseline to last study visit was –2.0 mmol/L for EXTRANEAL patients and + 0.6 mmol/L for control patients. Similar changes in serum chemistries were observed in an additional clinical study in a subpopulation of high average/high transporter patients. The declines in serum sodium and chloride may be related to dilution resulting from the presence of icodextrin metabolites in plasma. Although these decreases have been small and clinically unimportant, monitoring of the patients' serum electrolyte levels as part of routine blood chemistry testing is recommended.

EXTRANEAL does not contain potassium. Evaluate serum potassium prior to administering potassium chloride to the patient. In situations where there is a normal serum potassium level or hypokalemia, addition of potassium chloride (up to a concentration of 4 mEq/L) to the solution may be necessary to prevent severe hypokalemia. This should be made under careful evaluation of serum and total body potassium, and only under the direction of a physician.

Fluid, hematology, blood chemistry, electrolyte concentrations, and bicarbonate should be monitored periodically. If serum magnesium levels are low, magnesium supplements may be used.

Alkaline Phosphatase

An increase in mean serum alkaline phosphatase has been observed in clinical studies of ESRD patients receiving EXTRANEAL. No associated increases in liver function tests were observed. Serum alkaline phosphatase levels did not show evidence of progressive increase over a 12-month study period. Levels returned to normal approximately two weeks after discontinuation of EXTRANEAL.

There were individual cases where increased alkaline phosphatase was associated with elevated AST (SGOT), but neither elevation was considered causally related to treatment.

Drug Interactions

General

No clinical drug interaction studies were performed. No evaluation of EXTRANEAL's effects on the cytochrome P450 system was conducted. As with other dialysis solutions, blood concentrations of dialyzable drugs may be reduced by dialysis. Dosage adjustment of concomitant medications may be necessary. In patients using cardiac glycosides (digoxin and others), plasma levels of calcium, potassium and magnesium must be carefully monitored.

Insulin

A clinical study in 6 insulin-dependent diabetic patients demonstrated no effect of EXTRANEAL on insulin absorption from the peritoneal cavity or on insulin's ability to control blood glucose when insulin was administered intraperitoneally with EXTRANEAL. However, appropriate monitoring (See **PRECAUTIONS, Drug/Laboratory Test Interactions**) of blood glucose should be performed when initiating EXTRANEAL in diabetic patients and insulin dosage should be adjusted if needed (See **PRECAUTIONS**).

Heparin

No human drug interaction studies with heparin were conducted. *In vitro* studies demonstrated no evidence of incompatibility of heparin with EXTRANEAL.

Antibiotics

No human drug interaction studies with antibiotics were conducted. *In vitro* studies evaluating the minimum inhibitory concentration (MIC) of vancomycin, cefazolin, ampicillin, ampicillin/flucoxacillin, ceftazidime, gentamicin, and amphotericin demonstrated no evidence of incompatibility of these antibiotics with EXTRANEAL. (See **DOSAGE AND ADMINISTRATION**)

Drug/Laboratory Test Interactions

Blood Glucose

Blood glucose measurement must be done with a glucose-specific method to prevent maltose interference with test results. Falsely elevated glucose levels have been observed with blood glucose monitoring devices and test strips that use glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ), glucose-dye-oxidoreductase (GDO), and some glucose dehydrogenase flavin-adenine nucleotide (GDH-FAD)-based methods. GDH-PQQ,glucose-dye-oxidoreductase, and some GDH-FAD-based methods must not be used to measure glucose levels in patients administered EXTRANEAL. (See **WARNINGS**).

Serum Amylase

An apparent decrease in serum amylase activity has been observed in patients administered EXTRANEAL. Preliminary investigations indicate that icodextrin and its metabolites interfere with enzymatic-based amylase assays, resulting in inaccurately low values. This should be taken into account when evaluating serum amylase levels for diagnosis or monitoring of pancreatitis in patients using EXTRANEAL.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Icodextrin did not demonstrate evidence of genotoxicity potential in *in vitro* bacterial cell reverse mutation assay (Ames test); *in vitro* mammalian cell chromosomal aberration assay (CHO cell assay); and in the *in vivo* micronucleus assay in rats. Long-term animal studies to evaluate the carcinogenic potential of EXTRANEAL or icodextrin have not been conducted. Icodextrin is derived from maltodextrin, a common food ingredient.

A fertility study in rats where males and females were treated for four and two weeks, respectively, prior to mating and until day 17 of gestation at up to 1.5 g/kg/day (1/3 the human exposure on a mg/m^2 basis) revealed slightly low epididymal weights in parental males in the high dose group as compared to Control. Toxicological significance of this finding was not evident as no other reproductive organs were affected and all males were of proven fertility. The study demonstrated no effects of treatment with icodextrin on mating performance, fertility, litter response, embryo-fetal survival, or fetal growth and development.

Pregnancy

Pregnancy Category C

Complete animal reproduction studies including *in utero* embryofetal development at appreciable multiples of human exposure have not been conducted with EXTRANEAL or icodextrin. Thus it is not known whether icodextrin or EXTRANEAL solution can cause fetal harm when administered to a pregnant woman or affect reproductive capacity. EXTRANEAL should only be utilized in pregnant women when the need outweighs the potential risks.

Nursing Mothers

It is not known whether icodextrin or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when EXTRANEAL is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No formal studies were specifically carried out in the geriatric population. However, 140 of the patients in clinical studies of EXTRANEAL were age 65 or older, with 28 of the patients age 75 or older. No overall differences in safety or effectiveness were observed between these patients and patients under age 65. Although clinical experience has not identified differences in responses between the elderly and younger patients, greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

Clinical Trials

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

EXTRANEAL was originally studied in controlled clinical trials of 493 patients with end-stage renal disease who received a single daily exchange of EXTRANEAL for the long dwell (8-to 16- hours). There were 215 patients exposed for at least 6 months and 155 patients exposed for at least one year. The population was 18-83 years of age, 56% male and 44% female, 73% Caucasian, 18% Black, 4% Asian, 3% Hispanic, and it included patients with the following comorbid conditions: 27% diabetes, 49% hypertension and 23% hypertensive nephropathy.

Rash was the most frequently occurring EXTRANEAL-related adverse event (5.5%, EXTRANEAL; 1.7% Control). Seven patients on EXTRANEAL discontinued treatment due to rash, and one patient on EXTRANEAL discontinued due to exfoliative dermatitis. The rash typically appeared within the first three weeks of treatment and resolved with treatment discontinuation or, in some patients, with continued treatment.

Female patients reported a higher incidence of skin events, including rash, in both EXTRANEAL and dextrose control treatment groups.

Table 1 shows the adverse events reported in these clinical studies, regardless of causality, occurring in ≥ 5% of patients and more common on EXTRANEAL than control.

Table 1 - Adverse Experiences in ≥5 % of Patients and More Common on EXTRANEAL

	EXTRANEAL N = 493	Control N = 347
Peritonitis	26%	25%
Upper respiratory infection	15%	13%
Hypertension	13%	8%
Rash	10%	5%
Headache	9%	7%
Abdominal pain	8%	6%
Flu syndrome	7%	6%
Nausea	7%	5%
Cough increase	7%	4%
Edema	6%	5%
Accidental injury	6%	4%
Chest pain	5%	4%
Dyspepsia	5%	4%
Hyperglycemia	5%	4%

Adverse reactions reported with an incidence of > 5% and at least as common on dextrose control included pain, asthenia, exit site infection, infection, back pain, hypotension, diarrhea, vomiting, nausea/vomiting, anemia, peripheral edema, hypokalemia, hyperphosphatemia, hypoproteinemia, hypervolemia, arthralgia, dizziness, dyspnea, skin disorder, pruritis.

Additional adverse events occurring at an incidence of < 5% and that may or may not have been related to EXTRANEAL include: pain on infusion, abdominal enlargement, cloudy effluent, ultrafiltration decrease, postural hypotension, heart failure, hyponatremia, hypochloremia, hypercalcemia, hypoglycemia, alkaline phosphatase increase, SGPT increase, SGOT increase, cramping, confusion, lung edema, facial edema, exfoliative dermatitis, eczema, vesicobullous rash, maculopapular rash, erythema multiforme. All reported events are included in the list except those already listed in Table 1 or the following two paragraphs, those not plausibly associated with EXTRANEAL, and those that were associated with the condition being treated or related to the dialysis procedure.

EXTRANEAL was additionally studied in a subpopulation of 92 high average/high transporter APD patients in a two-week controlled clinical trial where patients received a single daily exchange of EXTRANEAL (n=47) or dextrose control (n=45) for the long dwell (14 ± 2 hours). Consistent with the data reported in the original trials of EXTRANEAL, rash was the most frequently occurring event.

Peritoneal Dialysis-Related
Adverse events common to the peritoneal dialysis, including peritonitis, infection around the catheter, fluid and electrolyte imbalance, and pain, were observed at a similar frequency with EXTRANEAL and Controls (See **PRECAUTIONS**).

Changes in Alkaline Phosphatase and Serum Electrolytes

An increase in mean serum alkaline phosphatase has been observed in clinical studies of ESRD patients receiving EXTRANEAL. No associated increases in other liver chemistry tests were observed. Serum alkaline phosphatase levels did not show progressive increase over a 12-month study period. Levels returned to normal approximately two weeks after discontinuation of EXTRANEAL.

Decreases in serum sodium and chloride have been observed in patients using EXTRANEAL. The declines in serum sodium and chloride may be related to dilution resulting from the presence of icodextrin metabolites in plasma. Although these decreases have been small and clinically unimportant, monitoring of patients' serum electrolyte levels as part of routine blood chemistry testing is recommended.

Post-Marketing

The following adverse reactions have been identified during post-approval use of EXTRANEAL. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to estimate their frequency reliably or to establish a causal relationship to drug exposure. Adverse reactions are listed by MedDRA System Order Class (SOC), followed by Preferred Term in order of severity.

INFECTIONS AND INFESTATIONS: Fungal peritonitis, Peritonitis bacterial, Catheter site infection, Catheter related infection

BLOOD AND LYMPHATIC SYSTEM DISORDERS: Thrombocytopenia, Leukopenia

IMMUNE SYSTEM DISORDERS: Leukocytoclastic vasculitis, Serum sickness, Hypersensitivity

METABOLISM AND NUTRITION DISORDERS: Shock hypoglycemia, Fluid overload, Dehydration, Fluid imbalance

NERVOUS SYSTEM DISORDERS: Hypoglycemic coma, Burning sensation

EYE DISORDERS: Vision blurred

RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS: Bronchospasm, Stridor

GASTROINTESTINAL DISORDERS: Sclerosing encapsulating peritonitis, Aseptic peritonitis, Peritoneal cloudy effluent, Ileus, Ascites, Inguinal hernia, Abdominal discomfort

SKIN AND SUBCUTANEOUS DISORDERS: Toxic epidermal necrolysis, Erythema multiforme, Angioedema, Urticaria generalized, Toxic skin eruption, Swelling face, Periorbital edema, Exfoliative rash, Skin exfoliation, Prurigo, Rash (including macular, papular, erythematous, exfoliative), Dermatitis (including allergic and contact), Drug eruption, Erythema, Onychomadesis, Dry skin, Skin chapped, Blister

MUSCULOSKELETAL, CONNECTIVE TISSUE DISORDERS: Arthralgia, Back pain, Musculoskeletal pain

REPRODUCTIVE SYSTEM AND BREAST DISORDERS: Penile edema, Scrotal edema

GENERAL DISORDERS AND ADMINISTRATIVE SITE CONDITIONS: Discomfort, Pyrexia, Chills, Malaise, Drug effect decreased, Drug ineffective, Catheter site erythema, Catheter site inflammation, Infusion related reaction (including Infusion site pain, Instillation site pain)

DRUG ABUSE AND DEPENDENCE

There has been no observed potential of drug abuse or dependence with EXTRANEAL.

OVERDOSAGE

No data are available on experiences of overdosage with EXTRANEAL. Overdosage of EXTRANEAL would be expected to result in higher levels of serum icodextrin and metabolites, but it is not known what signs or symptoms might be caused by exposure in excess of the exposures used in clinical trials. In the event of overdosage with EXTRANEAL, continued peritoneal dialysis with glucose-based solutions should be provided.

DOSAGE AND ADMINISTRATION

EXTRANEAL is intended for intraperitoneal administration only. It should be administered only as a single daily exchange for the long dwell in continuous ambulatory peritoneal dialysis or automated peritoneal dialysis. The recommended dwell time is 8- to 16- hours.

Not for intravenous injection.

Patients should be carefully monitored to avoid under- or over-hydration. An accurate fluid balance record must be kept and the patient's body weight monitored to avoid potentially severe consequences including congestive heart failure, volume depletion, and hypovolemic shock.

Aseptic technique should be used throughout the peritoneal dialysis procedure.

To reduce possible discomfort during administration, solutions may be warmed prior to use. (See **DOSAGE AND ADMINISTRATION, Directions for Use**).

EXTRANEAL should be administered over a period of 10-20 minutes at a rate that is comfortable for the patient.

Do not use EXTRANEAL if it is cloudy or discolored, if it contains particulate matter, or if the container is leaky.

Following use, the drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis.

For single use only. Discard unused portion.

Addition of Potassium

Potassium is omitted from EXTRANEAL solutions because dialysis may be performed to correct hyperkalemia. In situations where there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. The decision to add potassium chloride should be made by the physician after careful evaluation of serum potassium.

Addition of Insulin
Addition of insulin to EXTRANEAL was evaluated in 6 insulin-dependent diabetic patients undergoing CAPD for end stage renal disease. No interference of EXTRANEAL with insulin absorption from the peritoneal cavity or with insulin's ability to control blood glucose was observed. (See **PRECAUTIONS, Drug/ Laboratory Test Interactions**). Appropriate monitoring of blood glucose should be performed when initiating EXTRANEAL in diabetic patients and insulin dosage adjusted if needed (See **PRECAUTIONS**).

Addition of Heparin
No human drug interaction studies with heparin were conducted. *In vitro* studies demonstrated no evidence of incompatibility of heparin with EXTRANEAL.

Addition of Antibiotics
No formal clinical drug interaction studies have been performed. *In vitro* compatibility studies with EXTRANEAL (icodextrin) and the following antibiotics have demonstrated no effects with regard to minimum inhibitory concentration (MIC): vancomycin, cefazolin, ampicillin, ampicillin/flucoxacillin, ceftazidime, gentamicin, and amphotericin. However, aminoglycosides should not be mixed with penicillins due to chemical incompatibility.

Patients undergoing peritoneal dialysis should be under careful supervision of a physician experienced in the treatment of end-stage renal disease with peritoneal dialysis. It is recommended that patients being placed on peritoneal dialysis should be appropriately trained in a program that is under supervision of a physician.

Directions for Use

For complete CAPD and APD system preparation, see directions accompanying ancillary equipment.

Aseptic technique should be used.

Warming

For patient comfort, EXTRANEAL can be warmed to 37°C (98°F). Only dry heat should be used. It is best to warm solutions within the overwrap using a heating pad. Do not immerse EXTRANEAL in water for warming. Do not use a microwave oven to warm EXTRANEAL. Heating above 40°C (104°F) may be detrimental to the solution.

To Open

To open, tear the overwrap down at the slit and remove the solution container. Some opacity of the plastic, due to moisture absorption during the sterilization process, may be observed. This does not affect the solution quality or safety and may often leave a slight amount of moisture within the overwrap.

Inspect for Container Integrity

Inspect the container for signs of leakage and check for minute leaks by squeezing the container firmly.

Adding Medications

Some drug additives may be incompatible with EXTRANEAL.

See **DOSAGE AND ADMINISTRATION** section for additional information. If the re-sealable rubber plug on the medication port is missing or partly removed, do not use the product if medication is to be added.

1. Put on mask. Clean and/or disinfect hands.
2. Prepare medication port site using aseptic technique.
3. Using a syringe with a 1-inch long, 25- to 19-gauge needle, puncture the medication port and inject additive.
4. Reposition container with container ports up and evacuate medication port by squeezing and tapping it.
5. Mix solution and additive thoroughly.

Preparation for Administration

1. Put on mask. Clean and/or disinfect hands.
2. Place EXTRANEAL on work surface.
3. Remove pull ring from connector of solution container. If continuous fluid flow from connector is observed, discard solution container.
4. Remove tip protector from tubing set and immediately attach to connector of solution container.
5. Continue with therapy set-up as instructed in user manual or directions accompanying tubing sets.
6. Upon completion of therapy, discard any unused portion.

HOW SUPPLIED

EXTRANEAL (icodextrin) Peritoneal Dialysis Solution is available in the following containers and fill volumes:

Container	Fill Volume	NDC
ULTRABAG	1.5 L	NDC 0941-0679-51
ULTRABAG	2.0 L	NDC 0941-0679-52
ULTRABAG	2.5 L	NDC 0941-0679-53
AMBU-FLEX III	1.5 L	NDC 0941-0679-45
AMBU-FLEX III	2.0 L	NDC 0941-0679-47
AMBU-FLEX III	2.5 L	NDC 0941-0679-48
AMBU-FLEX II	2.0 L	NDC 0941-0679-06
AMBU-FLEX II	2.5 L	NDC 0941-0679-05

Each 100 mL of EXTRANEAL contains 7.5 grams of icodextrin in an electrolyte solution with 40 mEq/L lactate.

Store at 20–25°C (68–77°F). Excursions permitted to 15–30°C (59–86°F) [See USP Controlled Room Temperature]. Store in moisture barrier overwrap in carton until ready to use. Protect from freezing.

Rx Only

Baxter, Extraneal, UltraBag, and Ambu-Flex are trademarks of Baxter International Inc.

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Baxter

MEDICATION GUIDE

EXTRANEAL (X-tra-neel)
(icodextrin)
Peritoneal Dialysis Solution

Read the Medication Guide that comes with EXTRANEAL before you begin treatment and each time you receive a carton of EXTRANEAL. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about EXTRANEAL?

EXTRANEAL (icodextrin) contains maltose, which can react with certain blood glucose (blood sugar) monitors and test strips.

- Using EXTRANEAL may cause a false (incorrect) high blood sugar reading or may hide a blood sugar reading that is actually very low. This can happen if you use a glucose monitor or test strips with glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) glucose-dye-oxidoreductase (GDO), or glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) at any time during treatment or within approximately 2 weeks (14 days) after you stop treatment with EXTRANEAL. This kind of false reading means that your blood sugar may really be too low even though the test says that it is normal or high. This can lead to dangerous side effects.
- You could accidentally wait too long to treat your low blood sugar if you have low blood sugar and do not use the right kind of monitor and test strips.
- You could accidentally take too much insulin if you have a false high blood sugar reading.
- **Taking too much insulin or waiting too long to treat low blood sugar can cause you to have serious reactions including: loss of consciousness (passing out), coma, permanent neurological problems, or death.**
- If you have high blood sugar or diabetes and monitor your blood glucose, you must use a specific glucose monitor and test strips during treatment with EXTRANEAL and up to 2 weeks after stopping EXTRANEAL.
- Do not use blood glucose monitors or test strips that use glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO). Some blood glucose monitors or test strips that use glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) also must not be used.
- You, or your nurse or doctor should call the manufacturer of your blood glucose monitor and test strips to make sure that the maltose in EXTRANEAL (icodextrin) will not affect your blood sugar test results.
- **If you are hospitalized or go to an emergency room, tell the hospital staff that you use EXTRANEAL so that they use the right kind of blood sugar monitor and test strips for you.**
- You can get information on glucose monitor and test strip methods from their manufacturers. For a list of toll free numbers for glucose monitor and test strip manufacturers, you can ask your doctor or go to www.glucosesafety.com.

What is EXTRANEAL?

EXTRANEAL is a prescription peritoneal dialysis solution. EXTRANEAL draws fluid and wastes from your bloodstream into your peritoneal cavity (the space inside your abdomen). The fluids and wastes are removed from your body when the EXTRANEAL solution is drained.

EXTRANEAL is for the long dwell exchange (8 hours to 16 hours) in peritoneal dialysis. The long dwell is the exchange that lasts 8 hours or more:

- the nighttime exchange if you are on continuous ambulatory peritoneal dialysis (CAPD)
- the daytime exchange if you are using a cycler

EXTRANEAL is not for intravenous injection (injection into a vein).

It is not known if EXTRANEAL is safe and works in children.

Who should not use EXTRANEAL?

Do not use EXTRANEAL if:

- you have a glycogen storage disease
- you do not tolerate maltose or isomaltose
- you have severe lactic acidosis
- you are allergic to cornstarch or icodextrin

What should I tell my doctor before using EXTRANEAL?

EXTRANEAL may not be right for you. **Before using EXTRANEAL, tell your doctor about all your medical conditions, including if you:**

- have a condition that affects your nutrition, or you are not able to eat well
- have a lung or breathing problem
- have low potassium levels in your blood
- have high calcium levels in your blood
- have low magnesium levels in your blood
- have had recent aortic graft surgery
- have had stomach area (abdomen):
  - surgery in the past 30 days
  - tumors
  - open wounds
  - hernia
  - infection
- have certain bowel conditions, including
  - a colostomy or ileostomy
  - frequent episodes of diverticulitis
  - inflammatory bowel disease
- are pregnant or plan to become pregnant. It is not known if EXTRANEAL will harm your unborn baby.
- are breast-feeding. It is not known if EXTRANEAL passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. The dose of certain medicines may need to be changed when you use EXTRANEAL. Especially tell your doctor if you take:

- insulin
- blood pressure medicine
- digoxin (Lanoxicaps, Lanoxin, Lanoxin Pediatric)

Know the medicines you take. Keep a list of them and show your doctor and pharmacist when you get a new medicine.

How should I use EXTRANEAL?

- Use EXTRANEAL exactly as prescribed by your doctor.
- Use EXTRANEAL only for your long dwell exchange, and not more than 1 exchange in 24 hours.

Follow the steps that you learned in your peritoneal dialysis training to do your EXTRANEAL exchange.

- To open EXTRANEAL, tear the overwrap at the slit and remove the bag of solution.
- Before using EXTRANEAL, always check to make sure:
  - the bag does not leak. A small amount of moisture inside the overwrap is normal. Firmly squeeze the bag to check for small leaks.
  - the expiration date has not passed. Do not use EXTRANEAL after the expiration date shown on the carton and product label.
- Look at the bag to make sure the solution is clear and does not contain particles. Do not use a bag of EXTRANEAL if it is cloudy or contains particles.
- Before using EXTRANEAL, you may warm the bag in the overpouch, to make it more comfortable. Only use dry heat, such as a heating pad, to warm the EXTRANEAL solution to 98.6°F (37°C).
- Do not microwave EXTRANEAL. You can damage the solution if it gets hotter than 104°F (40°C).
- To avoid an increased risk of infection, do not put EXTRANEAL in water to heat the bag.
- To prevent a serious infection, you must:
  - clean (disinfect) your work surface (where you set your PD supplies) before starting your exchange.
  - use the technique that you were shown in your peritoneal dialysis training to prevent contamination with bacteria (aseptic technique), when making connections.
- If you use a manual method of peritoneal dialysis (CAPD), infuse EXTRANEAL over 10 to 20 minutes at a rate that is comfortable for you.
- When you drain the fluid after the dwell, check the drained fluid for cloudiness or fibrin. Fibrin looks like clumps or stringy material in the drained solution. Cloudy drained fluid or fibrin may mean that you have an infection. Call your doctor if your drained fluid is cloudy or contains fibrin.
- Regularly check and write down your fluid balance and weight to avoid having too much or too little fluid in your body (over-hydration or dehydration). This can help lessen the chance of serious side effects, such as heart failure and shock.
- Call your dialysis center or doctor if you need more help or have any questions.
- If you infuse too much EXTRANEAL, your stomach area (abdomen) may look large, and you may feel "full" or feel short of breath. If this happens, drain the EXTRANEAL solution from your peritoneal cavity.
- Talk to your doctor before adding any other medicines to EXTRANEAL.
- Throw away any unused EXTRANEAL. Do not use your EXTRANEAL solution more than one time.

What are possible side effects of EXTRANEAL?

EXTRANEAL can cause serious side effects, including:

- **See "What is the most important information I should know about EXTRANEAL?"**
- **Serious allergic reactions.** Tell your doctor or get medical help right away if you get any of these symptoms of a serious allergic reaction during treatment with EXTRANEAL:
  - swelling of your face, eyes, lips, tongue or mouth
  - trouble swallowing or breathing
  - skin rash, hives, sores in your mouth, on your eyelids, or in your eyes
  - your skin blisters and peels

Common side effects of EXTRANEAL include:

- infection in the peritoneal cavity (peritonitis). Peritonitis is common in people on peritoneal dialysis. Tell your doctor right away if you have any pain, redness, fever, or cloudy drained fluid.
- high blood pressure
- headache
- stomach area (abdomen) pain
- increased cough
- flu-like symptoms
- nausea
- swelling
- chest pain
- upset stomach
- high blood sugar

These are not all the possible side effects of EXTRANEAL. For more information, ask your doctor or dialysis center.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store EXTRANEAL?

- Store EXTRANEAL at 68°F to 77°F (20° to 25°C).
- Keep EXTRANEAL in the moisture barrier overpouch in the carton until ready to use.
- Do not warm EXTRANEAL above 104°F (40°C).
- Do not freeze EXTRANEAL.

General information about EXTRANEAL

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use EXTRANEAL for a condition for which it was not prescribed. Do not give EXTRANEAL to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about EXTRANEAL. If you would like more information, talk with your doctor. You can ask your doctor for information about EXTRANEAL that is written for healthcare professionals. You can also find out more about EXTRANEAL by calling your doctor or visiting the website www.renalinfo.com.

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*BAR CODE POSITION ONLY

Dianeal® PD-2 Peritoneal Dialysis Solution

UltraBag™ System For Continuous Ambulatory Peritoneal Dialysis (CAPD)

For intraperitoneal administration only

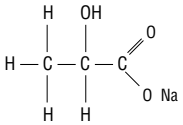
Description

Dianeal® PD-2 peritoneal dialysis solutions are sterile, nonpyrogenic solutions in UltraBag™ containers for intraperitoneal administration only. They contain no bacteriostatic or antimicrobial agents.

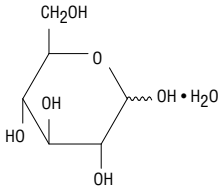
UltraBag™ containers are designed with an integrated "Y" set and drain container for infusion and drainage of Dianeal® PD-2 when disconnection of the "Y" set from the transfer set during dwell is desired.

Composition, calculated osmolarity, pH, and ionic concentrations are shown in the following table.

	Composition/100 mL							Ionic Concentration (mEq/L)					How Supplied			
	Dextrose, Hydrous, USP	Sodium Chloride, USP ($NaCl$)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	**OSMOLARITY (mOsmol/L) (calc)**	pH	Sodium	Calcium	Magnesium	Chloride	Lactate	Fill Volume (mL)	Container Size (mL)	Code	NDC
Dianeal® PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose	1.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**346**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9865 5B9866 5B9868 5B9857	0941-0426-51 0941-0426-52 0941-0426-53 0941-0426-55
Dianeal® PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose	2.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**396**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9875 5B9876 5B9878 5B9858	0941-0427-51 0941-0427-52 0941-0427-53 0941-0427-55
Dianeal® PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose	4.25 g	538 mg	448 mg	25.7 mg	5.08 mg	**485**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9895 5B9896 5B9898 5B9859	0941-0429-51 0941-0429-52 0941-0429-53 0941-0429-55



Sodium Lactate



Dextrose Hydrous, USP
(D-Glucopyranose monohydrate)

The plastic container tubing set is fabricated from polyvinyl chloride (PL 146® Plastic). Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. The amount of water that can permeate from inside the solution container into the overpouch is insufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

Clinical Pharmacology

Peritoneal dialysis is a procedure for removing toxic substances and metabolites normally excreted by the kidneys, and for aiding in the regulation of fluid and electrolyte balance.

The procedure is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. Toxic substances and metabolites, present in high concentration in the blood, cross the peritoneal membrane into the dialyzing fluid. Dextrose in the dialyzing fluid is used to produce a solution hyperosmolar to the plasma, creating an osmotic gradient which facilitates fluid removal from the patient's plasma into the peritoneal cavity. After a period of time, (dwell time), the fluid is drained by gravity from the cavity.

The solution does not contain potassium. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. **Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.**

Clinical studies have demonstrated the use of this solution resulted in significant increases in serum CO_2 and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

Indications and Usage

Dianeal® PD-2 peritoneal dialysis solutions in UltraBag™ containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

Contraindications

None known.

Warnings

Not for Intravenous Injection.

Use aseptic technique. Contamination of Luer lock connector may result in peritonitis.

An improper clamping sequence may result in infusion of air into the peritoneum.

Peritoneal dialysis should be done with great care, if at all, in patients with a number of conditions, including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, large polycystic kidneys, recent aortic graft replacement, lactic acidosis, and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences, including congestive heart failure, volume depletion, and shock.

Excessive use of Dianeal® PD-2 peritoneal dialysis solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.

If the resealable rubber plug on the medication port is missing or partially removed, do not use product.

After removing overpouch, check for minute leaks by squeezing container firmly. If leaks are found, discard the solution because the sterility may be impaired.

After the pull ring has been removed from the outlet, check for broken connector frangible seal as evidenced by continuous fluid flow from port. A few drops of solution within the connector or protector cap may be present. If a continuous stream or droplets of fluid are noted, discard solution because sterility may be impaired.

During solution drainage, fibrin strands may be observed in the solution and may become attached to the connector frangible closure. In occasional instances, partial or complete obstruction of draining may occur. Manipulation of the connector frangible closure in the tubing may free the fibrin obstruction.

Precautions

General: Do not administer unless solution is clear.

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.

Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysis treatment and therapy directed at other existing illnesses. For example, rapid potassium removal may create arrhythmias in cardiac patients using digitalis or similar drugs; digitalis toxicity may be masked by elevated potassium or magnesium, or by hypocalcemia. Correction of electrolytes by dialysis may precipitate signs and symptoms of digitalis excess. Conversely, toxicity may occur at suboptimal dosages of digitalis if potassium is low or calcium high. Azotemic diabetics require careful monitoring of insulin requirements during and following dialysis with dextrose containing solutions.

Laboratory tests:
Serum electrolytes, magnesium, bicarbonate levels and fluid balance should be periodically monitored.

Carcinogenesis, mutagenesis, impairment of fertility:
Long term animal studies with Dianeal® PD-2 peritoneal dialysis solution have not been performed to evaluate the carcinogenic potential, mutagenic potential or effect on fertility.

Pregnancy: Teratogenic Effects
Pregnancy Category C. Animal reproduction studies have not been conducted with Dianeal® PD-2 peritoneal dialysis solution. It is also not known whether Dianeal® PD-2 peritoneal dialysis solution can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dianeal® PD-2 peritoneal dialysis solution should be given to a pregnant woman only if clearly needed.

Nursing mothers:
Caution should be exercised when Dianeal® PD-2 peritoneal dialysis solution is administered to a nursing woman.

Pediatric use:
Safety and effectiveness in children have not been established.

Adverse Reactions

Adverse reactions to peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around the peritoneal catheter, catheter site infection, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions may include peritonitis, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypotension, hypertension, disequilibrium syndrome, allergic symptoms, and muscle cramping.

Dosage and Administration

Dianeal® PD-2 solutions are intended for intraperitoneal administration only.

It is recommended that adult patients being placed on continuous ambulatory peritoneal dialysis should be appropriately trained in a program which is under the supervision of a physician. Training materials are available from Baxter Healthcare Corporation, Deerfield, IL, 60015 USA to facilitate this training.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

The frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for and supervising the treatment of the individual patient.

To avoid the risk of severe dehydration and hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with the lowest level of osmolarity consistent with the fluid removal requirements for that exchange.

Heating the dialysis solution to 37°C (98.6°F) may decrease discomfort.

Additives may be incompatible. Do not store solution containing additives.

Two liters of dialysis solution are instilled into the peritoneal cavity of adults and the peritoneal access device is then clamped. The solution remains in the cavity for dwell times of 4 to 8 hours during the day and 8 to 12 hours overnight. At the conclusion of each dwell period, the access device is opened, the solution drained and fresh solution instilled. The procedure is repeated 3 to 5 times per day, 6 to 7 days per week. Solution exchange frequency should be individualized for adequate biochemical and fluid volume control. The majority of exchanges will utilize 1.5% or 2.5% dextrose containing peritoneal dialysis solutions, with 4.25% dextrose containing solutions being used when extra fluid removal is required. Patient weight is used as the indicator of the need for fluid removal.

Directions for Use

Use aseptic technique.

For complete system preparation, see directions accompanying ancillary equipment.

Preparation for Administration

1. Gather supplies.
2. Tear the container overpouch firmly down the side from top slit and remove. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity should diminish gradually.
3. Place container on work surface.
4. Uncoil tubing.
5. Inspect the patient connector to ensure the pull ring is attached. Do not use if pull ring is not attached to the connector.
6. Inspect tubing and drain container for presence of solution. If solution is noted, discard units. NOTE: Small water droplets are acceptable.
7. Squeeze container to check for leaks and broken solution frangible. Note solution flow past the frangible. Discard if container or solution frangible leaks, because sterility may be impaired.

If Supplemental Medication is Prescribed:

1. Inspect container to ensure resealable rubber medication port is in place. Discard if rubber injection port is not attached to container port.
2. Put on a mask.
3. Prepare medication port according to aseptic technique.
4. Using a syringe with a 1 inch long, 19 to 25 gauge needle, puncture resealable medication port and inject medication.
5. Position container with medication port facing upward. Squeeze and tap medication port to empty solution. Mix solution by vigorously agitating container.

Administration:

1. Put on mask and wash hands.
2. Insure patient transfer set is closed.
3. Break connector frangible (blue) by grasping the tubing above the top of the frangible and pulling forward and backward until the frangible separates from base. See Figures 1 and 2.
4. Remove pull ring from the patient connector.
5. Remove disconnect cap from patient transfer set. **Immediately** attach patient transfer set connector to the patient connector by twisting the connector until firmly secured.
6. Clamp solution line.
7. Break solution frangible (green) by grasping the tubing above the top of the frangible and pulling forward and backward until the frangible separates. See Figures 3 and 4.
8. Hang the new solution container.
9. Place the drainage container below the level of the peritoneum.
10. Open transfer set clamp to drain solution from peritoneum. **Warning:** During solution drainage, fibrin strands may become attached to the connector frangible closure. Manipulation of the connector frangible closure in the tubing may free any fibrin obstruction that occurs.
11. Close transfer set line clamp after drainage is complete.
12. Open solution line clamp and allow the new solution to flow into the drainage container for 5 seconds to prime line.
13. Clamp drain line.
14. Open transfer set clamp and allow the solution to flow into the peritoneum.
15. Close transfer set clamp when infusion is complete.
16. Prepare a new disconnect cap following the directions accompanying the cap.
17. Disconnect the patient transfer set connection from the UltraBag™ and attach a new disconnect cap to the transfer set.

How Supplied

Dianeal® PD-2 peritoneal dialysis solutions in UltraBag™ containers are available in nominal size flexible containers as shown in the table in the DESCRIPTION section.

All Dianeal® PD-2 peritoneal dialysis solutions have overfills which are declared on container labeling.

Freezing of solution may occur at temperatures below 0°C (32°F). Allow to thaw naturally in ambient conditions and thoroughly mix contents by shaking.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F).

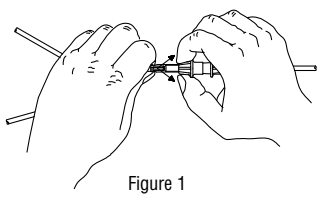


Figure 1

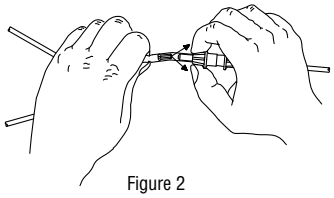


Figure 2

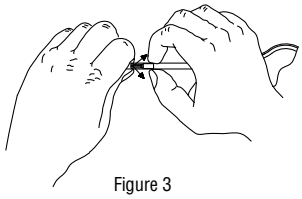


Figure 3

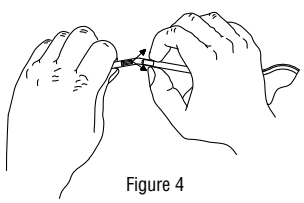
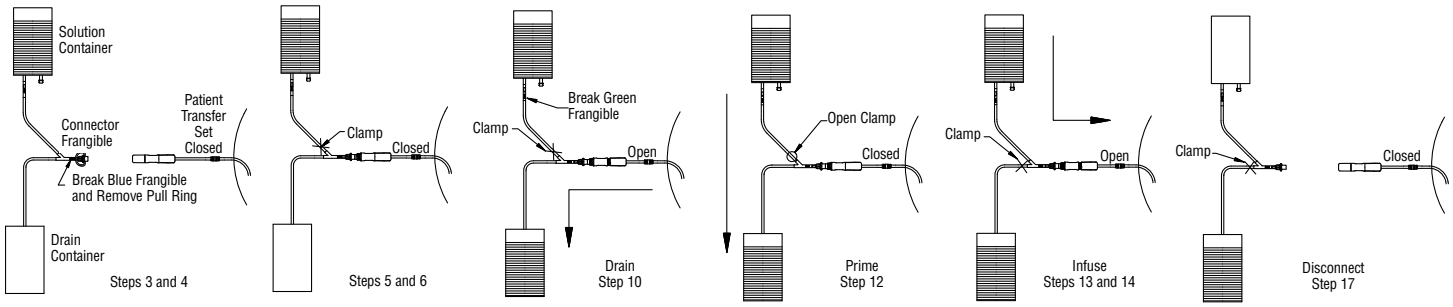


Figure 4

Administration Procedure for the UltraBag™ Container Exchange

(The Steps Refer to the Corresponding Administration Steps)



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DIANEAL PD-2 Peritoneal Dialysis Solution

AMBU-FLEX Container For Peritoneal Dialysis

For intraperitoneal administration only

Description

DIANEAL PD-2 peritoneal dialysis solutions in AMBU-FLEX containers are sterile, nonpyrogenic solutions for intraperitoneal administration only. They contain no bacteriostatic or antimicrobial agents or added buffers.

Composition, calculated osmolarity, pH, and ionic concentrations are shown in Table 1.

Potassium is omitted from DIANEAL solutions because dialysis may be performed to correct hyperkalemia. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. **Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.** Frequent monitoring of serum electrolytes is indicated.

Because average plasma magnesium levels in some chronic CAPD patients have been observed to be elevated (Nolph et al. 1981), the magnesium concentration of this formulation has been reduced to 0.5 mEq/L. Average plasma magnesium levels have not been reported for chronic IPD and CCPD patients. Serum magnesium levels should be monitored and if low, oral magnesium supplements, oral magnesium containing phosphate binders, or peritoneal dialysis solutions containing higher magnesium concentrations may be used.

Because average serum bicarbonate levels in some chronic CAPD patients (Nolph et al. 1981), some chronic IPD patients (La Greca et al. 1980), and some chronic CCPD patients (Diaz-Buxo et al. 1983) have been observed to be somewhat lower than normal values, the bicarbonate precursor (lactate) concentration of this formulation has been raised to 40 mEq/L. Serum bicarbonate levels should be monitored.

The osmolarities shown in Table 1 are calculated values. As an example, measured osmolarity by freezing point depression determination of DIANEAL PD-2 peritoneal dialysis solution with 1.5% dextrose is approximately

334 mOsmol/L, compared with measured values in normal human serum of 280 mOsmol/L.

The plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

Clinical Pharmacology

Peritoneal dialysis is a procedure for removing toxic substances and metabolites normally excreted by the kidneys, and for aiding in the regulation of fluid and electrolyte balance.

The procedure is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. With the exception of lactate, present as a bicarbonate precursor, electrolyte concentrations in the fluid have been formulated to attempt to normalize plasma electrolyte concentrations resulting from osmosis and diffusion across the peritoneal membrane (between the plasma of the patient and the dialysis fluid). Toxic substances and metabolites, present in high concentrations in the blood, cross the peritoneal membrane into the dialyzing fluid. Dextrose in the dialyzing fluid is used to produce a solution hyperosmolar to the plasma, creating an osmotic gradient which facilitates fluid removal from the patient's plasma into the peritoneal cavity. After a period of time (dwell time), the fluid is drained from the cavity.

Indications and Usage

Peritoneal dialysis is indicated for patients in acute or chronic renal failure when nondialytic medical therapy is judged to be inadequate (Vaamonde and Perez 1977). It may also be indicated in the treatment of certain fluid and electrolyte disturbances, and for patients intoxicated with certain poisons and drugs (Knepshield et al. 1977). However, for many substances other methods of detoxification have been reported to be more effective than peritoneal dialysis (Vaamonde and Perez 1977; Chang 1977).

Contraindications

None known

Warnings

Peritoneal dialysis should be done with great care, if at all, in patients with a number of abdominal conditions including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, and large polycystic kidneys (Vaamonde and Perez 1977). Other conditions include recent aortic graft replacement and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences including congestive heart failure, volume depletion, and shock.

Excessive use of DIANEAL PD-2 peritoneal dialysis solution with 3.5% or 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

In acute renal failure patients, plasma electrolyte concentrations should be monitored periodically during the procedure. Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.

Because average plasma magnesium levels in chronic CAPD patients have been observed to be elevated (Nolph et al. 1981), the magnesium concentration of this formulation has been reduced to 0.5 mEq/L. Average plasma magnesium levels have not been reported for chronic IPD and CCPD patients. Serum magnesium levels should be monitored and if low, oral magnesium supplements, oral magnesium containing phosphate binders, or peritoneal dialysis solutions containing higher magnesium concentrations may be used.

Because average serum bicarbonate levels in some chronic CAPD patients (Nolph et al. 1981), some chronic IPD patients (La Greca et al. 1980), and some chronic CCPD patients (Diaz-Buxo et al. 1983), have been observed to be somewhat lower than normal values, the bicarbonate precursor (lactate) concentration of this formulation has been raised to 40 mEq/L. Serum bicarbonate levels should be monitored.

Not for use in the treatment of lactic acidosis.

Potassium is omitted from DIANEAL PD-2 solutions because dialysis may be performed to correct hyperkalemia. **Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.**

The use of 5 or 6 liters of dialysis solution is not indicated in a single exchange.

Refer to manufacturer's directions accompanying drugs to obtain full information on additives.

If the resealable rubber plug on the medication port is missing or partially removed, do not use product if medication is to be added.

After the pull ring has been removed, inspect connector of solution container for fluid flow. A few drops of solution within the connector or pull ring may be present due to condensation of water resulting from the sterilization process. If a continuous stream of fluid is noted, discard solution because sterility may be impaired.

After removing overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard the solution because the sterility may be impaired.

Freezing of solution may occur at temperatures below 0°C (32°F). Do not flex or manipulate container when frozen. Allow container to thaw naturally in ambient conditions and thoroughly mix contents by shaking.

Precautions

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection. If peritonitis occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to identification of the involved organism(s), broad-spectrum antibiotics may be indicated.

Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. Solutions should not be heated in water due to an increased risk of infection. Microwave ovens should not be used to heat solutions because there is a potential for damage to the solution container. Moreover, microwave oven heating may potentially cause overheating and/or non-uniform heating of the solution that may result in patient injury or discomfort.

Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

Pregnancy: Teratogenic Effects Pregnancy Category C. Animal reproduction studies have not been conducted with DIANEAL peritoneal dialysis solutions. It is also not known whether DIANEAL peritoneal dialysis solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DIANEAL peritoneal dialysis solutions should be given to a pregnant woman only if clearly needed.

Do not administer unless solution is clear and seal is intact.

Adverse Reactions

Adverse reactions to peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around a chronic peritoneal catheter, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions may include electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, hypotension, disequilibrium syndrome, and muscle cramping.

Dosage and Administration

DIANEAL PD-2 solutions are intended for intraperitoneal administration only.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

The mode of therapy (Intermittent Peritoneal Dialysis [IPD], Continuous Ambulatory Peritoneal Dialysis [CAPD], or Continuous Cyclic Peritoneal Dialysis [CCPD]), frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for and supervising the treatment of the individual patient.

To avoid the risk of severe dehydration and hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with the lowest level of osmolarity consistent with the fluid removal requirements for that exchange.

Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. (See Directions for Use)

The addition of heparin to the dialysis solution may be indicated to aid in prevention of catheter blockage in patients with peritonitis, or when the solution drainage contains fibrinous or proteinaceous material (Ribot et al. 1966). 1000 to 2000 USP units of heparin per liter of solution has been recommended for adults (Furman et al. 1978). For children, 50 units of heparin per 100 mL of dialysis fluid has been recommended (Irwin et al. 1981).

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgement of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

Intermittent Peritoneal Dialysis (IPD)

For maintenance dialysis of chronic renal failure patients.

The cycle of instillation, dwell and removal of dialysis fluid is repeated sequentially over a period of hours (8 to 36 hours) as many times per week as indicated by the condition of the patient. For chronic renal failure patients, maintenance dialysis is often accomplished by periodic dialysis (3 to 5 times weekly) for shorter time periods (8 to 14 hours per session) (Mattocks and El-Bassiouni 1971).

Continuous Ambulatory Peritoneal Dialysis (CAPD) and Continuous Cyclic Peritoneal Dialysis (CCPD)

For maintenance dialysis of chronic renal failure patients.

In CAPD, 1.5 to 3.0 liters of dialysis solution (depending upon patient size) are instilled into the peritoneal cavity of adults and the peritoneal access device is then clamped (Kim et al. 1984; Twardowski and Janicka 1981; Twardowski and Burrows 1984). For children, 30 to 50 mL/kg body weight with a maximum of 2 liters has been recommended (Potter et al. 1981; Irwin et al. 1981). The solution remains in the cavity for dwell times of 4 to 8 hours during the day and 8 to 12 hours overnight. At the conclusion of each dwell period, the access device is opened, the solution drained and fresh solution instilled. The procedure is repeated 3 to 5 times per day, 6 to 7 days per week. Solution exchange volumes and frequency of exchanges should be individualized for adequate biochemical and fluid volume control (Moncrief et al. 1982; Twardowski et al. 1983). The majority of exchanges will utilize 1.5% or 2.5% dextrose containing peritoneal dialysis solutions, with 3.5% or 4.25% dextrose containing solutions being used when extra fluid removal is required. Patient weight is used as the indicator of the need for fluid removal (Popovich et al. 1978).

In CCPD, the patient receives 3 or 4 dialysis exchanges during the night which range from 2-1/2 to 3 hours dwell duration. Typically 1.5 to 2.0 liters of dialysis solution (depending upon patient size) are delivered each cycle by an automatic peritoneal dialysis cycler machine. After the last outflow during the night, an additional exchange is infused by the cycler machine into the peritoneum. The equipment is then disconnected from the patient, and the dialysate remains in the peritoneum for 14 to 15 hours during the day until the next nocturnal cycle (Diaz-Buxo et al. 1981). Combinations of 1.5% or 2.5% dextrose containing peritoneal dialysis solutions are usually used for the nighttime exchanges, while 3.5% or 4.25% dextrose is used when extra fluid removal is required such as during the daytime exchange. Patient weight is used as the indicator of the need for fluid removal (Popovich et al. 1978) so therapy should be individualized according to the patient's need for ultrafiltration.

It is recommended that adult patients being placed on chronic peritoneal dialysis or, in the case of pediatric patients, the selected caretaker, (as well as the patient, when suitable), should be appropriately trained in a program which is under the supervision of a physician. Training materials are available from Baxter Healthcare Corporation, Deerfield, IL 60015, USA to facilitate this training.

How Supplied

DIANEAL PD-2 peritoneal dialysis solutions in AMBU-FLEX II and AMBU-FLEX III containers are available in nominal size flexible containers with fill volumes and dextrose concentrations as indicated in Table 1.

All DIANEAL PD-2 peritoneal dialysis solutions have overfills which are declared on container labeling.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F): brief exposure up to 40°C (104°F) does not adversely affect the product.

Directions for Use

Use aseptic technique.

For complete system preparation, see directions accompanying ancillary equipment.

Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. Solutions should not be heated in water due to an increased risk of infection. Microwave ovens should not be used to heat solutions because there is a potential for damage to the solution container. Moreover, microwave oven heating may potentially cause overheating and/or non-uniform heating of the solution that may result in patient injury or discomfort.

To Open

Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. If supplemental medication is desired, follow directions below before preparing for administration. Check for minute leaks by squeezing container firmly.

To Add Medication

Additives may be incompatible.

If the resealable rubber plug on the medication port is missing or partially removed, do not use product if medication is to be added.

1. Put on mask. Clean and/or disinfect hands.
2. Prepare medication site using aseptic technique.
3. Using a syringe with a 1 inch long 19 to 25 gauge needle, puncture resealable medication port and inject medication.
4. Position container with ports up and evacuate the medication port by squeezing and tapping it.
5. Mix solution and medication thoroughly.

Preparation for Administration

1. Put on mask. Clean and/or disinfect hands.
2. Place solution container on work surface.
3. Remove pull ring from connector of the solution container. If continuous fluid flow from connector is observed, discard solution container.
4. Remove tip protector from tubing set and immediately attach to connector of the solution container.
5. Continue with therapy set-up as instructed in user manual or directions accompanying tubing sets.
6. Upon completion of therapy, discard unused portion.

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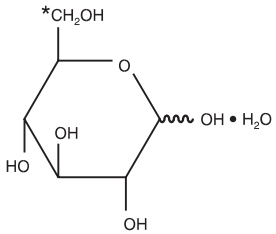
Table 1

	Composition/100 mL					Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)					How Supplied			
	* Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2$*$2H_2O$)	Magnesium Chloride, USP ($MgCl2$*$6H2O$)			Sodium	Calcium	Magnesium	Chloride	Lactate	Fill Volume (mL)	Container Size (mL)	Code	NDC
DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose AMBU-FLEX II Container	1.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**346**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1000 2000 2500 3000 5000 6000	1000 3000 3000 3000 6000 6000	L5B5163 L5B5166 L5B5168 L5B5169 L5B5193 L5B9710	NDC 0941-0411-05 NDC 0941-0411-06 NDC 0941-0411-08 NDC 0941-0411-04 NDC 0941-0411-07 NDC 0941-0411-11
DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose AMBU-FLEX III Container	1.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**346**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	250 500 750 1000 1500 2000 2500 3000 5000 6000	500 1000 1000 1000 2000 2000 3000 3000 5000 6000	5B5160 5B5161 5B5162 5B5163 5B5165 5B5166 5B5168 5B5169 5B5193 5B9710	NDC 0941-0411-40 NDC 0941-0411-41 NDC 0941-0411-42 NDC 0941-0411-43 NDC 0941-0411-45 NDC 0941-0411-46 NDC 0941-0411-48 NDC 0941-0411-49 NDC 0941-0411-25 NDC 0941-0411-28
DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose AMBU-FLEX II Container	2.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**396**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1000 2000 2500 3000 5000 6000	1000 3000 3000 3000 6000 6000	L5B5173 L5B5177 L5B5178 L5B5179 L5B5194 L5B9711	NDC 0941-0413-05 NDC 0941-0413-06 NDC 0941-0413-08 NDC 0941-0413-04 NDC 0941-0413-07 NDC 0941-0413-01
DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose AMBU-FLEX III Container	2.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**396**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	250 500 750 1000 1000 1500 2000 2500 3000 5000 6000	500 1000 1000 1000 2000 2000 3000 3000 5000 6000	5B5170 5B5171 5B5172 5B5173 5B5174 5B5175 5B5177 5B5178 5B5179 5B5194 5B9711	NDC 0941-0413-40 NDC 0941-0413-41 NDC 0941-0413-42 NDC 0941-0413-43 NDC 0941-0413-44 NDC 0941-0413-45 NDC 0941-0413-47 NDC 0941-0413-48 NDC 0941-0413-49 NDC 0941-0413-25 NDC 0941-0413-28
DIANEAL PD-2 Peritoneal Dialysis Solution with 3.5% Dextrose AMBU-FLEX III Container	3.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**447**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	2500	3000	5B4804	NDC 0941-0423-48
DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose AMBU-FLEX II Container	4.25 g	538 mg	448 mg	25.7 mg	5.08 mg	**485**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1000 2000 2500 3000 5000 6000	1000 3000 3000 3000 6000 6000	L5B5183 L5B5187 L5B5188 L5B5189 L5B5195 L5B9712	NDC 0941-0415-05 NDC 0941-0415-06 NDC 0941-0415-08 NDC 0941-0415-04 NDC 0941-0415-07 NDC 0941-0415-01
DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose AMBU-FLEX III Container	4.25 g	538 mg	448 mg	25.7 mg	5.08 mg	**485**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	250 500 750 1000 1000 1500 2000 2500 3000 5000 6000	500 1000 1000 1000 2000 2000 3000 3000 3000 5000 6000	5B5180 5B5181 5B5182 5B5183 5B5184 5B5185 5B5187 5B5188 5B5189 5B5195 5B9712	NDC 0941-0415-40 NDC 0941-0415-41 NDC 0941-0415-42 NDC 0941-0415-43 NDC 0941-0415-44 NDC 0941-0415-45 NDC 0941-0415-47 NDC 0941-0415-48 NDC 0941-0415-49 NDC 0941-0415-25 NDC 0941-0415-28



Dextrose Hydrous, USP
(D-Glucopyranose monohydrate)

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DIANEAL Low Calcium Peritoneal Dialysis Solution

AMBU-FLEX Container For Peritoneal Dialysis

For intraperitoneal administration only

Description

DIANEAL Low Calcium peritoneal dialysis solutions in AMBU-FLEX containers are sterile, nonpyrogenic solutions for intraperitoneal administration only. They contain no bacteriostatic or antimicrobial agents or added buffers.

Composition, calculated osmolarity, pH and ionic concentrations are shown in Table 1.

Potassium is omitted from peritoneal dialysis solutions because dialysis may be performed to correct hyperkalemia. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. **Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.** Frequent monitoring of serum electrolytes is indicated.

In some patients calcium carbonate is used as a phosphate binder. Because serum calcium levels have been observed to be elevated in these patients (Slatopolsky et al. 1986), the calcium concentration of DIANEAL Low Calcium peritoneal dialysis solutions has been reduced to 2.5 mEq/L. Serum calcium levels should be monitored and if low, the amount of oral calcium carbonate phosphate binder may be increased or peritoneal dialysis solutions containing higher calcium concentrations may be used. If serum calcium levels rise, adjustments to the dosage of the calcium carbonate phosphate binder and/or vitamin D analogs should be considered by the physician.

Because average plasma magnesium levels in some chronic CAPD patients have been observed to be elevated (Nolph et al. 1981), the magnesium concentration of this formulation has been reduced to 0.5 mEq/L. Average plasma magnesium levels have not been reported for chronic IPD and CCPD patients. Serum magnesium levels should be monitored and if low, oral magnesium supplements, oral magnesium containing phosphate binders, or peritoneal dialysis solutions containing higher magnesium concentrations may be used.

Because average serum bicarbonate levels in some chronic CAPD patients (Nolph et al. 1981), some chronic IPD patients (La Greca et al. 1980), and some chronic CCPD patients (Diaz-Buxo et al. 1983) have been observed to be somewhat lower than normal values, the bicarbonate precursor (lactate) concentration of DIANEAL Low Calcium peritoneal dialysis solutions has been raised to 40 mEq/L. Serum bicarbonate levels should be monitored.

The osmolarities shown in Table 1 are calculated values. Calculated osmolarity of DIANEAL Low Calcium peritoneal dialysis solution with 1.5% dextrose is 344 mOsmol/L, compared with measured values in normal human serum of 280 mOsmol/L.

The plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overpouch is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

Clinical Pharmacology

Peritoneal dialysis is a procedure for removing toxic substances and metabolites normally excreted by the kidneys, and for aiding in the regulation of fluid and electrolyte balance.

The procedure is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. With the exception of lactate, present as a bicarbonate precursor, electrolyte concentrations in the fluid have been formulated in an attempt to normalize plasma electrolyte concentrations resulting from osmosis and diffusion across the peritoneal membrane (between the patient's plasma and the dialysis fluid). Toxic substances and metabolites, present in high concentrations in the blood, cross the peritoneal membrane into the dialyzing fluid. Dextrose in the dialyzing fluid is used to produce a solution hyperosmolar to the plasma, creating an osmotic gradient which facilitates fluid removal from the patient's plasma into the peritoneal cavity. After a period of time (dwell time), the fluid is drained from the cavity.

Indications and Usage

DIANEAL Low Calcium peritoneal dialysis solutions are indicated for use in chronic renal failure patients being maintained on peritoneal dialysis.

Contraindications

None known.

Warnings

Peritoneal dialysis should be done with great care, if at all, in patients with a number of abdominal conditions including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, and large polycystic kidneys (Vaamonde and Perez 1977). Other conditions include recent aortic graft replacement and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences including congestive heart failure, volume depletion, and shock.

Excessive use of DIANEAL Low Calcium peritoneal dialysis solution with 3.5% or 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.

In some patients calcium carbonate is used as a phosphate binder. Because serum calcium levels have been observed to be elevated in these patients (Slatopolsky et al. 1986), the calcium concentration of DIANEAL Low Calcium peritoneal dialysis solutions has been reduced to 2.5 mEq/L. Serum calcium levels should be monitored and if low, the amount of oral calcium carbonate phosphate binder may be increased or peritoneal dialysis solutions containing higher calcium concentrations may be used. If serum calcium levels rise, adjustments to the dosage of the calcium carbonate phosphate binder and/or vitamin D analogs should be considered by the physician.

Because average plasma magnesium levels in some chronic CAPD patients have been observed to be elevated (Nolph et al. 1981), the magnesium concentration of this formulation has been reduced to 0.5 mEq/L. Average plasma magnesium levels have not been reported for chronic IPD and CCPD patients. Serum magnesium levels should be monitored and if low, oral magnesium supplements, oral magnesium containing phosphate binders, or peritoneal dialysis solutions containing higher magnesium concentrations may be used.

Because average serum bicarbonate levels in some chronic CAPD patients (Nolph et al. 1981), some chronic IPD patients (La Greca et al. 1980), and some chronic CCPD patients (Diaz-Buxo et al. 1983), have been observed to be somewhat lower than normal values, the bicarbonate precursor (lactate) concentration of DIANEAL Low Calcium peritoneal dialysis solutions has been raised to 40 mEq/L. Serum bicarbonate levels should be monitored.

Not for use in the treatment of lactic acidosis.

Potassium is omitted from DIANEAL Low Calcium peritoneal dialysis solutions because dialysis may be performed to correct hyperkalemia. **Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.**

The use of 5 or 6 liters of dialysis solution is not indicated in a single exchange.

Refer to manufacturer's directions accompanying drugs to obtain full information on additives.

If the resealable rubber plug on the medication port is missing or partially removed, do not use product if medication is to be added.

After the pull ring has been removed, inspect connector of solution container for fluid flow. A few drops of solution within the connector or pull ring may be present due to condensation of water resulting from the sterilization process. If a continuous stream of fluid is noted, discard solution because sterility may be impaired.

After removing overpouch, check for minute leaks by squeezing container firmly. If leaks are found, discard the solution because the sterility may be impaired.

Freezing of solution may occur at temperatures below 0°C (32°F). Allow to thaw naturally in ambient conditions and thoroughly mix contents by shaking.

Precautions

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection. If peritonitis occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to identification of the involved organism(s), broad-spectrum antibiotics may be indicated.

Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. Solutions should not be heated in water due to an increased risk of infection. Microwave ovens should not be used to heat solutions because there is a potential for damage to the solution container. Moreover, microwave oven heating may potentially cause overheating and/or non-uniform heating of the solution that may result in patient injury or discomfort.

Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with DIANEAL Low Calcium peritoneal dialysis solutions. It is also not known whether DIANEAL Low Calcium peritoneal dialysis solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DIANEAL Low Calcium peritoneal dialysis solutions should be given to a pregnant woman only if clearly needed.

Do not administer unless solution is clear and seal is intact.

Adverse Reactions

Adverse reactions to peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around a chronic peritoneal catheter, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions may include electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, hypotension, disequilibrium syndrome, and muscle cramping.

When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysis treatment and therapy directed at other existing illnesses. For example, rapid potassium removal may create arrhythmias in cardiac patients using digitalis or similar drugs; digitalis toxicity may be masked by elevated potassium or magnesium, or by hypocalcemia. Correction of electrolytes by dialysis may precipitate signs and symptoms of digitalis excess. Conversely, toxicity may occur at suboptimal dosages of digitalis if potassium is low or calcium high. Azotemic diabetics require careful monitoring of insulin requirements during and following dialysis with dextrose containing solutions.

Dosage and Administration

DIANEAL Low Calcium peritoneal dialysis solutions are intended for intraperitoneal administration only.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

The mode of therapy (Intermittent Peritoneal Dialysis [IPD], Continuous Ambulatory Peritoneal Dialysis [CAPD], or Continuous Cyclic Peritoneal Dialysis [CCPD]), frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for and supervising the treatment of the individual patient.

To avoid the risk of severe dehydration and hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with the lowest level of osmolarity consistent with the fluid removal requirements for that exchange.

Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. (See Directions for Use)

The addition of heparin to the dialysis solution may be indicated to aid in prevention of catheter blockage in patients with peritonitis, or when the solution drainage contains fibrinous or proteinaceous material (Ribot et al. 1966). 1000 to 2000 USP units of heparin per liter of solution has been recommended for adults (Furman et al. 1978). For children, 50 units of heparin per 100 mL of dialysis fluid has been recommended (Irwin et al. 1981).

Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

Intermittent Peritoneal Dialysis (IPD)

For maintenance dialysis of chronic renal failure patients.

The cycle of instillation, dwell and removal of dialysis fluid is repeated sequentially over a period of hours (8 to 36 hours) as many times per week as indicated by the condition of the patient. For chronic renal failure patients, maintenance dialysis is often accomplished by periodic dialysis (3 to 5 times weekly) for shorter time periods (8 to 14 hours per session) (Mattocks and El-Bassiouni 1971).

Continuous Ambulatory Peritoneal Dialysis (CAPD) and Continuous Cyclic Peritoneal Dialysis (CCPD)

For maintenance dialysis of chronic renal failure patients.

In CAPD, typically 1.5 to 3.0 liters of dialysis solution (depending upon patient size) are instilled into the peritoneal cavity of adults and the peritoneal access device is then clamped (Kim et al. 1984; Twardowski and Janicka 1981; Twardowski and Burrows 1984). For children, 30 to 50 mL/kg body weight with a maximum of 2 liters has been recommended (Potter et al. 1981; Irwin et al. 1981). The solution remains in the cavity for dwell times of 4 to 8 hours during the day and 8 to 12 hours overnight. At the conclusion of each dwell period, the access device is opened, the solution drained and fresh solution instilled. The procedure is repeated 3 to 5 times per day, 6 to 7 days per week. Solution exchange volumes and frequency of exchanges should be individualized for adequate biochemical and fluid volume control (Moncrief et al. 1982; Twardowski et al. 1983). The majority of exchanges will utilize 1.5% or 2.5% dextrose containing peritoneal dialysis solutions, with 3.5% or 4.25% dextrose containing solutions being used when extra fluid removal is required. Patient weight is used as the indicator of the need for fluid removal (Popovich et al. 1978).

In CCPD, the patient receives 3 or 4 dialysis exchanges during the night which range from 2-1/2 to 3 hours dwell duration. Typically 1.5 to 2.0 liters of dialysis solution (depending upon patient size) are delivered each cycle by an automatic peritoneal dialysis cycler machine. After the last outflow during the night, an additional exchange is infused by the cycler machine into the peritoneum. The equipment is then disconnected from the patient, and the dialysate remains in the peritoneum for 14 to 15 hours during the day until the next nocturnal cycle (Diaz-Buxo et al. 1981). Combinations of 1.5% or 2.5% dextrose containing peritoneal dialysis solutions are usually used for the nighttime exchanges, while 3.5% or 4.25% dextrose containing solution is used when extra fluid removal is required such as during the daytime exchange. Patient weight is used as the indicator of the need for fluid removal (Popovich et al. 1978) so therapy should be individualized according to the patient's need for ultrafiltration.

It is recommended that adult patients being placed on peritoneal dialysis or, in the case of pediatric patients, the selected caretaker, (as well as the patient, when suitable), should be appropriately trained in a program which is under the supervision of a physician. Training materials are available from Baxter Healthcare Corporation, Deerfield, IL 60015 USA to facilitate this training.

How Supplied

DIANEAL Low Calcium peritoneal dialysis solutions in AMBU-FLEX II and AMBU-FLEX III containers are available in nominal size flexible containers with fill volumes as indicated in Table 1.

All DIANEAL Low Calcium peritoneal dialysis solutions have overfills which are declared on container labeling.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F): brief exposure up to 40°C (104°F) does not adversely affect the product.

Directions for Use

Use aseptic technique.

For complete system preparation, see directions accompanying ancillary equipment.

Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. Solutions should not be heated in water due to an increased risk of infection. Microwave ovens should not be used to heat solutions because there is a potential for damage to the solution container. Moreover, microwave oven heating may potentially cause overheating and/or non-uniform heating of the solution that may result in patient injury or discomfort.

To Open

Tear overpouch down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. If supplemental medication is desired, follow directions below before preparing for administration. Check for minute leaks by squeezing container firmly.

To Add Medication

Additives may be incompatible.

If the resealable rubber plug on the medication port is missing or partially removed, do not use product if medication is to be added.

1. Put on mask. Clean and/or disinfect hands.
2. Prepare medication site using aseptic technique.
3. Using a syringe with a 1 inch long 19 to 25 gauge needle, puncture resealable medication port and inject medication.
4. Position container with ports up and evacuate the medication port by squeezing and tapping it.
5. Mix solution and medication thoroughly.

Preparation for Administration

1. Put on mask. Clean and/or disinfect hands.
2. Place solution container on work surface.
3. Remove pull ring from connector of the solution container. If continuous fluid flow from connector is observed, discard solution container.
4. Remove tip protector from tubing set and immediately attach to connector of the solution container.
5. Continue with therapy set-up as instructed in user manual or directions accompanying tubing sets.
6. Upon completion of therapy, discard unused portion.

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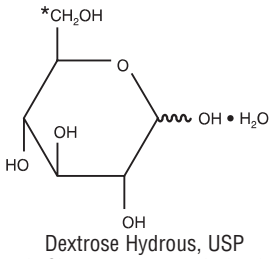
Table 1

	Composition/100 mL						Ionic Concentration (mEq/L)					How Supplied			
	* Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl2 \cdot 6H2O$)	**Osmolarity (mOsmol/L) (calc)**	pH	Sodium	Calcium	Magnesium	Chloride	Lactate	Fill Volume (mL)	Container Size (mL)	Code	NDC
DIANEAL Low Calcium Peritoneal Dialysis Solution with 1.5% Dextrose AMBU-FLEX II Container	1.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**344**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	2000 2500 3000 5000 6000	3000 3000 3000 6000 6000	L5B4825 L5B9718 L5B9901 L5B4826 L5B9770	NDC 0941-0409-06 NDC 0941-0409-08 NDC 0941-0409-05 NDC 0941-0409-07 NDC 0941-0409-01
DIANEAL Low Calcium Peritoneal Dialysis Solution with 1.5% Dextrose AMBU-FLEX III Container	1.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**344**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	1500 2000 2500 3000 5000 6000	2000 2000 3000 3000 5000 6000	5B9715 5B4825 5B9718 5B9901 5B4826 5B9770	NDC 0941-0409-45 NDC 0941-0409-36 NDC 0941-0409-48 NDC 0941-0409-49 NDC 0941-0409-27 NDC 0941-0409-28
DIANEAL Low Calcium Peritoneal Dialysis Solution with 2.5% Dextrose AMBU-FLEX II Container	2.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**395**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	2000 2500 3000 5000 6000	3000 3000 3000 6000 6000	L5B9727 L5B9728 L5B9902 L5B5202 L5B9771	NDC 0941-0457-08 NDC 0941-0457-07 NDC 0941-0457-02 NDC 0941-0457-05 NDC 0941-0457-01
DIANEAL Low Calcium Peritoneal Dialysis Solution with 2.5% Dextrose AMBU-FLEX III Container	2.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**395**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	1500 2000 2500 3000 5000 6000	2000 3000 3000 3000 5000 6000	5B9725 5B9727 5B9728 5B9902 5B5202 5B9771	NDC 0941-0457-45 NDC 0941-0457-47 NDC 0941-0457-48 NDC 0941-0457-49 NDC 0941-0457-25 NDC 0941-0457-28
DIANEAL Low Calcium Peritoneal Dialysis Solution with 3.5% Dextrose AMBU-FLEX III Container	3.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**445**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	2500	3000	5B9738	NDC 0941-0463-48
DIANEAL Low Calcium Peritoneal Dialysis Solution with 4.25% Dextrose AMBU-FLEX II Container	4.25 g	538 mg	448 mg	18.3 mg	5.08 mg	**483**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	2000 2500 3000 5000 6000	3000 3000 3000 6000 6000	L5B9747 L5B9748 L5B9903 L5B5203 L5B9772	NDC 0941-0459-08 NDC 0941-0459-07 NDC 0941-0459-02 NDC 0941-0459-05 NDC 0941-0459-01
DIANEAL Low Calcium Peritoneal Dialysis Solution with 4.25% Dextrose AMBU-FLEX III Container	4.25 g	538 mg	448 mg	18.3 mg	5.08 mg	**483**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	1500 2000 2500 3000 5000 6000	2000 3000 3000 3000 5000 6000	5B9745 5B9747 5B9748 5B9903 5B5203 5B9772	NDC 0941-0459-45 NDC 0941-0459-47 NDC 0941-0459-48 NDC 0941-0459-49 NDC 0941-0459-25 NDC 0941-0459-28



Dextrose Hydrous, USP
(D-Glucopyranose monohydrate)

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Dianeal® Low Calcium Peritoneal Dialysis Solution

UltraBag™ System For Continuous Ambulatory Peritoneal Dialysis (CAPD)

For intraperitoneal administration only

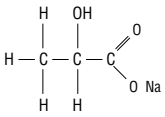
Description

Dianeal® Low Calcium peritoneal dialysis solutions are sterile, nonpyrogenic solutions in UltraBag™ containers for intraperitoneal administration only. They contain no bacteriostatic or antimicrobial agents.

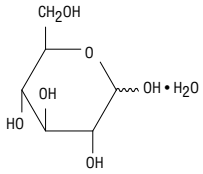
UltraBag™ containers are designed with an integrated "Y" set and drain container for infusion and drainage of Dianeal® Low Calcium when disconnection of the "Y" set from the transfer set during dwell is desired.

Composition, calculated osmolarity, pH and ionic concentrations are shown in the following table.

	Composition/100 mL					OSMOLARITY (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)					How Supplied			
	Dextrose, Hydrous, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)			Sodium	Calcium	Magnesium	Chloride	Lactate	Fill Volume (mL)	Container Size (mL)	Code	NDC
Dianeal® Low Calcium Peritoneal Dialysis Solution with 1.5% Dextrose	1.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**344**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9765 5B9766 5B9768 5B9757	0941-0424-51 0941-0424-52 0941-0424-53 0941-0424-55
Dianeal® Low Calcium Peritoneal Dialysis Solution with 2.5% Dextrose	2.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**395**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9775 5B9776 5B9778 5B9758	0941-0430-51 0941-0430-52 0941-0430-53 0941-0430-55
Dianeal® Low Calcium Peritoneal Dialysis Solution with 4.25% Dextrose	4.25 g	538 mg	448 mg	18.3 mg	5.08 mg	**483**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9795 5B9796 5B9798 5B9759	0941-0433-51 0941-0433-52 0941-0433-53 0941-0433-55



Sodium Lactate



Dextrose Hydrous, USP
(D-Glucopyranose monohydrate)

The plastic container tubing set is fabricated from polyvinyl chloride (PL 146® Plastic). Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. The amount of water that can permeate from inside the solution container into the overpouch is insufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

Clinical Pharmacology

Peritoneal dialysis is a procedure for removing toxic substances and metabolites normally excreted by the kidneys, and for aiding in the regulation of fluid and electrolyte balance.

The procedure is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. Toxic substances and metabolites, present in high concentration in the blood, cross the peritoneal membrane into the dialyzing fluid. Dextrose in the dialyzing fluid is used to produce a solution hyperosmolar to the plasma, creating an osmotic gradient which facilitates fluid removal from the patient's plasma into the peritoneal cavity. After a period of time, (dwell time), the fluid is drained by gravity from the cavity.

The solution does not contain potassium. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. **Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.**

Clinical studies have demonstrated the use of this solution resulted in significant increases in serum CO_2 and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

Indications and Usage

Dianeal® Low Calcium peritoneal dialysis solutions in UltraBag™ containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

Contraindications

None known.

Warnings

Not for Intravenous Injection.

Use aseptic technique. Contamination of Luer lock connector may result in peritonitis.

An improper clamping sequence may result in infusion of air into the peritoneum.

Peritoneal dialysis should be done with great care, if at all, in patients with a number of conditions, including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, large polycystic kidneys, recent aortic graft replacement, lactic acidosis, and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences, including congestive heart failure, volume depletion, and shock.

Excessive use of Dianeal® Low Calcium peritoneal dialysis solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.

If the resealable rubber plug on the medication port is missing or partially removed, do not use product.

After removing overpouch, check for minute leaks by squeezing container firmly. If leaks are found, discard the solution because the sterility may be impaired.

After the pull ring has been removed from the outlet, check for broken connector frangible seal as evidenced by continuous fluid flow from port. A few drops of solution within the connector or protector cap may be present. If a continuous stream or droplets of fluid are noted, discard solution because sterility may be impaired.

During solution drainage, fibrin strands may be observed in the solution and may become attached to the connector frangible closure. In occasional instances, partial or complete obstruction of draining may occur. Manipulation of the connector frangible closure in the tubing may free the fibrin obstruction.

Precautions

General: Do not administer unless solution is clear.

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.

Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysis treatment and therapy directed at other existing illnesses. For example, rapid potassium removal may create arrhythmias in cardiac patients using digitalis or similar drugs; digitalis toxicity may be masked by elevated potassium or magnesium, or by hypocalcemia. Correction of electrolytes by dialysis may precipitate signs and symptoms of digitalis excess. Conversely, toxicity may occur at suboptimal dosages of digitalis if potassium is low or calcium high. Azotemic diabetics require careful monitoring of insulin requirements during and following dialysis with dextrose containing solutions.

Laboratory tests:
Serum electrolytes, magnesium, bicarbonate levels and fluid balance should be periodically monitored.

Carcinogenesis, mutagenesis, impairment of fertility:
Studies to evaluate the carcinogenic or mutagenic potential of this product, or its potential to affect fertility adversely, have not been performed.

Pregnancy: Teratogenic Effects
Pregnancy Category C. Animal reproduction studies have not been conducted with Dianeal® Low Calcium peritoneal dialysis solution. It is also not known whether Dianeal® Low Calcium peritoneal dialysis solution can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dianeal® Low Calcium peritoneal dialysis solution should be given to a pregnant woman only if clearly needed.

Nursing mothers:
Caution should be exercised when Dianeal® Low Calcium peritoneal dialysis solution is administered to a nursing woman.

Pediatric use:
Safety and effectiveness in children have not been established.

Adverse Reactions

Adverse reactions to peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around the peritoneal catheter, catheter site infection, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions may include peritonitis, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypotension, hypertension, disequilibrium syndrome, allergic symptoms, and muscle cramping.

Dosage and Administration

Dianeal® Low Calcium solutions are intended for intraperitoneal administration only.

It is recommended that adult patients being placed on continuous ambulatory peritoneal dialysis should be appropriately trained in a program which is under supervision of a physician. Training materials are available from Baxter Healthcare Corporation, Deerfield, IL, 60015 USA to facilitate this training.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

The frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for and supervising the treatment of the individual patient.

To avoid the risk of severe dehydration and hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with the lowest level of osmolarity consistent with the fluid removal requirements for that exchange.

Heating the dialysis solution to 37˚C (98.6˚F) may decrease discomfort.

Additives may be incompatible. Do not store solution containing additives.

Approximately two liters of dialysis solution are instilled into the peritoneal cavity of adults and the peritoneal access device is then clamped. The solution remains in the cavity for dwell times of 4 to 8 hours during the day and 8 to 12 hours overnight. At the conclusion of each dwell period, the access device is opened, the solution drained and fresh solution instilled. The procedure is repeated 3 to 5 times per day, 6 to 7 days per week. Solution exchange frequency should be individualized for adequate biochemical and fluid volume control. The majority of exchanges will utilize 1.5% or 2.5% dextrose containing peritoneal dialysis solutions, with 4.25% dextrose containing solutions being used when extra fluid removal is required. Patient weight is used as the indicator of the need for fluid removal.

Directions for Use

Use aseptic technique.

For complete system preparation, see directions accompanying ancillary equipment.

Preparation for Administration

1. Gather supplies.
2. Tear the container overpouch firmly down the side from top slit and remove. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity should diminish gradually.
3. Place container on work station.
4. Uncoil tubing.
5. Inspect the patient connector to ensure the pull ring is attached. Do not use if pull ring is not attached to the connector.
6. Inspect tubing and drain container for presence of solution. If solution is noted, discard units. NOTE: Small water droplets are acceptable.
7. Squeeze container to check for leaks and broken solution frangible. Note solution flow past the frangible. Discard if container or solution frangible leaks, because sterility may be impaired.

If Supplemental Medication is Prescribed:

1. Inspect container to ensure resealable rubber medication port is in place. Discard if rubber injection port is not attached to container port.
2. Put on a mask.
3. Prepare medication port according to aseptic technique.
4. Using a syringe with a 1 inch long, 19 to 25 gauge needle, puncture resealable medication port and inject medication.
5. Position container with medication port facing upward. Squeeze and tap medication port to empty solution. Mix solution by vigorously agitating container.

Administration:

1. Put on mask and wash hands.
2. Insure patient transfer set is closed.
3. Break connector frangible (blue) by grasping the tubing above the top of the frangible and pulling forward and backward until the frangible separates from base. See Figures 1 and 2.
4. Remove pull ring from the patient connector.
5. Remove disconnect cap from patient transfer set. **Immediately** attach patient transfer set connector to the patient connector by twisting the connector until firmly secured.
6. Clamp solution line.
7. Break solution frangible (green) by grasping the tubing above the top of the frangible and pulling forward and backward until the frangible separates. See Figures 3 and 4.
8. Hang the new solution container.
9. Place the drainage container below the level of the peritoneum.
10. Open transfer set clamp to drain solution from peritoneum. Warning: During solution drainage, fibrin strands may become attached to the connector frangible closure. Manipulation of the connector frangible closure in the tubing may free any fibrin obstruction that occurs.
11. Close transfer set line clamp after drainage is complete.
12. Open solution line clamp and allow the new solution to flow into the drainage container for 5 seconds to prime line.
13. Clamp drain line.
14. Open transfer set clamp and allow the solution to flow into the peritoneum.
15. Close transfer set clamp when infusion is complete.
16. Prepare a new disconnect cap following the directions accompanying the cap.
17. Disconnect the patient transfer set from the UltraBag™ and attach a new disconnect cap to the transfer set.

How Supplied

Dianeal® Low Calcium peritoneal dialysis solutions in UltraBag™ containers are available in nominal size flexible containers as shown in the table in the DESCRIPTION section.

All Dianeal® Low Calcium peritoneal dialysis solutions have overfills which are declared on container labeling.

Freezing of solutions may occur at temperatures below 0˚C (32˚F). Allow to thaw naturally in ambient conditions and thoroughly mix contents by shaking.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25˚C/77˚F).

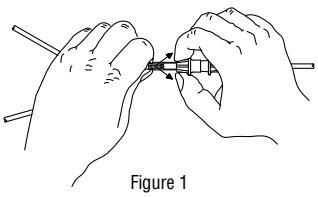


Figure 1

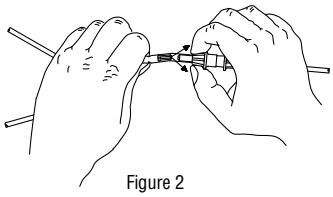


Figure 2

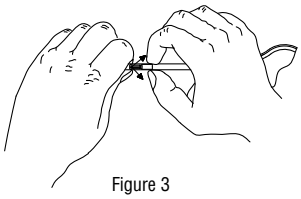


Figure 3

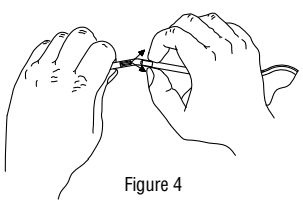
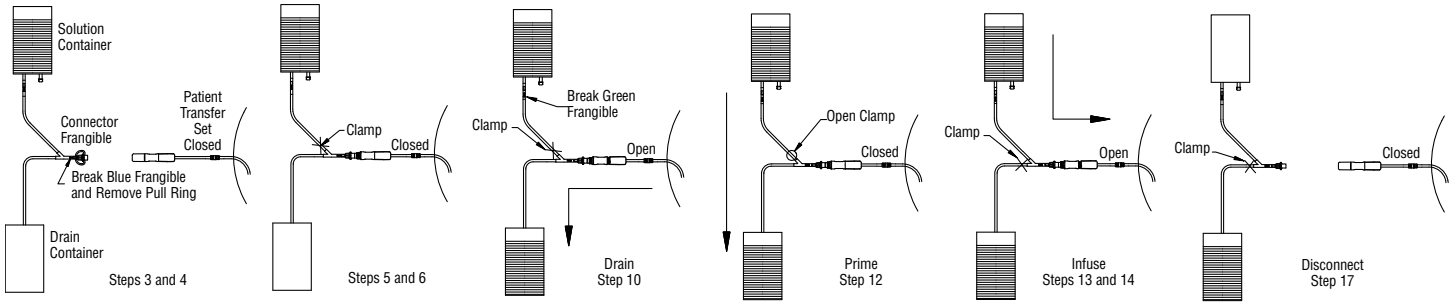


Figure 4

Administration Procedure for the UltraBag™ Container Exchange

(The Steps Refer to the Corresponding Administration Steps)



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